ASP®
STERRAD® 100NX®

STERRAD® 100NX® Sterilization System

User's Guide

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ADVANCED STERILIZATION PRODUCTS
Division of Ethicon, Inc.
a Johnson & Johnson company

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Division of Ethicon, Inc.
a Johnson&Johnson company
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Please visit www.aspjj.com
For warranty information, please visit our website or contact ASP Professional Services.

ASP International Customer Support; call your local ASP Representative

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Chapter 1.

Introduction

How to Use This Guide

If you are a STERRAD® 100NX® Sterilizer operator, **you must read** the “Safety Information, “ the “Introduction,” “Load Preparation,” and “Operation” chapters prior to operating the sterilizer. This “Introduction” explains the features and parts of the sterilizer. “Load Preparation” explains how to prepare and package instruments for processing. “Operation” explains how to operate the sterilizer and obtain optimal results.

If you are a supervisor overseeing the STERRAD® 100NX® Sterilizer, you should read the entire user’s guide and pay particular attention to the chapter featuring “Access Levels and Supervisor Level Tasks.” This chapter describes tasks and options that are only available through “Supervisor Level” access.

Intended Use

The STERRAD® 100NX® Sterilization System is a general purpose, low temperature sterilizer which uses the STERRAD® 100NX® Process to inactivate microorganisms on a broad range of medical devices and surgical instruments.

When used as directed by the instructions in this user’s guide, the STERRAD® 100NX® Sterilization System will sterilize both metal and nonmetal medical devices at low temperatures. Please review “How to Determine What Can Be Sterilized in the STERRAD® 100NX® Sterilizer” in the “Load Preparation” chapter along with the cycle information to make sure you follow the directions for processing items in each type of cycle.

The STERRAD® Sterilization Process

The STERRAD® 100NX® Sterilizer sterilizes medical devices by diffusing hydrogen peroxide vapor into the chamber and then electromagnetiy exciting the hydrogen peroxide molecules into a low-temperature plasma state. The combined use of hydrogen peroxide vapor and plasma safely and rapidly sterilizes medical instruments and materials without leaving toxic residue. All stages of the sterilization cycle operate within a dry environment at a low temperature, and thus the cycle is not damaging to compatible instruments that are sensitive to heat and moisture.

The STERRAD® 100NX® Sterilizer can be used for both metal and nonmetal devices, and can also sterilize instruments that have difficult-to-reach (diffusion-restricted) spaces, such as hinges on forceps. Refer to the "Safety Information" chapter for more information on device safety.

The sterilizer consistently provides a Sterility Assurance Level (SAL) of 10^{-6}, as defined by U.S. Food and Drug Administration (FDA) and international standards, for clinical use on all allowed substrates within the limits of the claims for materials and geometries when used in accordance with the directions in this user's guide.

If You Have Questions

If you have questions about the STERRAD® 100NX® Sterilizer or questions about which items may be safely sterilized by the STERRAD® Process, please call your local Advanced Sterilization Products (ASP) Representative or visit our website at www.aspjj.com.

Chapter 2.

Safety Information

Your safety is of primary concern to Advanced Sterilization Products (ASP). This chapter provides information on safely using the STERRAD® 100NX® Sterilizer. **You must read and understand the safety information in this chapter before operating the sterilizer.** Always pay attention to the warnings, cautions and notes throughout this user's guide. This information is for your safety and to ensure that you receive the most benefit from the safe operation of your STERRAD® 100NX® Sterilization System.

Personal Safety and First Aid

WARNING! HYDROGEN PEROXIDE IS CORROSIVE.

Concentrated hydrogen peroxide is corrosive to skin, eyes, nose, throat, lungs, and the gastrointestinal tract. Always wear chemical resistant latex, PVC (vinyl), or nitrile gloves while removing items from the sterilizer following a cancelled cycle or if any moisture is noted on items in the load following a completed cycle.

WARNING! HYDROGEN PEROXIDE IS AN OXIDIZER.

Hydrogen peroxide is strong oxidizing agent and poses a hazard for fire, explosion, or container rupture. Avoid allowing hydrogen peroxide to contact organic materials, including paper, cotton, wood, or lubricants. Do not use or store near heat or open flame. Shoes, clothing, or other combustible material that have come into contact with hydrogen peroxide must be immediately and thoroughly rinsed with water to avoid a potential fire hazard. In case of fire, use only water to extinguish.

WARNING! RISK OF EYE INJURY.

Direct hydrogen peroxide contact with eyes can cause irreversible tissue damage. If contact with eyes occurs, hold the eyes open and flush with large amounts of water for at least 15-20 minutes. Remove contact lenses, if present, and then continue rinsing the eyes. Consult a physician immediately after flushing the eyes.

WARNING! RISK OF SKIN INJURY.

Direct hydrogen peroxide contact with the skin can cause severe irritation. Wear chemical resistant latex, PVC (vinyl), or nitrile gloves when handling new, used, or ejected cassettes, items from a cancelled cycle, or items that have moisture present after a completed cycle. Immediately take off contaminated clothing and rinse thoroughly with water to avoid potential fire hazard and wash before re-use.

WARNING! RISK OF RESPIRATORY IRRITATION.

Inhalation of hydrogen peroxide mist can cause severe irritation of lungs, throat, and nose. If inhalation occurs, move to the person to fresh air. If the person is not breathing, call for emergency medical attention, or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Consult a physician immediately.

WARNING! CONCENTRATED HYDROGEN PEROXIDE IS TOXIC.

Ingestion of hydrogen peroxide may be life-threatening. If swallowed, call a “poison control” center or physician immediately for treatment advice. Have the person drink plenty of water if the person is able to swallow. Do not give anything by mouth to an unconscious person. Do not induce vomiting unless instructed to do so by the poison control center or physician.

WARNING! HEATED STERILIZATION SURFACES.

At the end of a cycle, the interior of the sterilizer may be hot. Do not touch the inside of the chamber or door with your bare or gloved hands. Allow the sterilizer to cool before touching interior surfaces.

WARNING! AVOID EXPOSURE TO ULTRAVIOLET LIGHT.

The hydrogen peroxide monitor uses an ultraviolet light source located inside the chamber behind the door. To avoid eye injury, do not stare directly at the ultraviolet light source for an extended period of time.

WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.

If white residue is visible on the load, this is residue from the hydrogen peroxide stabilizer. Wear chemical resistant latex, PVC (vinyl), or nitrile gloves when removing a load with visible white residue. White residue can be minimized by making sure regular Planned Maintenance procedures are performed on your system. The system will inform you when Planned Maintenance is due. Please schedule your PM service in a timely manner.

WARNING! RISK OF BREATHING DIFFICULTIES.

On rare occasions, the outlet filter on the vacuum pump can prematurely fail. If this occurs, you may see mist or what some users have described as “haze” or “smoke” in the room where the sterilizer is operating. The chemical composition of the mist is primarily airborne mineral oil with trace amounts of other compounds. Oil mist exposure may, theoretically, pose an increased risk to people with certain respiratory conditions, such as asthma, and they should take special precautions not to be exposed to the mist. If you observe these conditions, personnel should leave the room as a precaution and discontinue use of the STERRAD® System until the system is repaired. Personnel should avoid working in the room until the mist has cleared.

Please note that all STERRAD® Sterilizers should be used and installed in a well ventilated environment (a minimum of 10 air exchanges per hour).

Personal Protective Equipment

WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.

Wear chemical resistant latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.

Device Safety

WARNING! RISK OF INJURY OR DAMAGE TO STERILIZER.

The STERRAD® 100NX® Sterilizer should not be used stacked with other equipment.

CAUTION: RISK OF DAMAGE TO LOAD.

Metal objects must not come into contact with the chamber walls, the door, or the electrode. Contact with the walls, door, or electrode could damage the sterilizer or the metal objects.

CAUTION: KNOW WHAT YOU CAN PROCESS.

Before processing any item in the STERRAD® 100NX® Sterilizer, make sure you know how the STERRAD Sterilization Process will affect the item. Read, understand, and follow the medical device manufacturers' instructions for their products. This guide lists certain types of items and materials that can be safely processed in certain cycle choices. Make sure you understand the parameters of each cycle type before processing your items. This guide is not intended to replace any medical device manufacturers' instructions. If you have questions, or if you are in doubt about the materials in your devices, contact the medical device manufacturer or your ASP Customer Representative for more information.

CAUTION: RISK OF VIOLATION OF WARRANTY.

Improper processing may limit our liability for damage to processed instruments. Improper processing may also violate your instrument warranty.

CAUTION: RISK OF DAMAGE TO LOAD – METAL OBJECTS.

Metal objects must not come into contact with the chamber walls, the doors, or the electrode. Contact with the walls, doors, or electrode could damage the sterilizer or the metal objects.

CAUTION: RISK OF DAMAGE TO LOAD – VENTING CAPS.

Take special care to confirm that venting caps are placed according to the manufacturers' instructions. Venting caps are intended to prevent damage to flexible scopes that are being exposed to a vacuum, regardless of the sterilant used.

CAUTION: RISK OF DAMAGE TO LOAD – IMMERSION CAPS.

You *must remove* the water-resistant immersion cap (if present) prior to processing in the sterilizer. If the immersion cap is not removed prior to processing in the STERRAD® 100NX® Sterilizer, it will damage the flexible scope due to the inability to properly vent.

CAUTION: KNOW WHAT YOU CAN PROCESS – FLEXIBLE ENDOSCOPES.

Prior to processing flexible endoscopes in the STERRAD® 100NX® Sterilizer, you must read, understand, and follow the medical device manufacturer's instructions for use for the particular scope to be processed. Please contact the medical device manufacturer for more information on what can be processed in the STERRAD® 100NX® Sterilizer.

CAUTION: RF COMMUNICATIONS EQUIPMENT.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Guidance And Declaration-Electromagnetic Emissions		
The STERRAD® 100NX® Sterilizer is intended for use in the electromagnetic environment specified below. Assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The STERRAD® 100NX® Sterilizer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The STERRAD® 100NX® Sterilizer is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

System is configured with FCC ID: AXJ100NXRFID
or FCC ID: AXJ02532480 or contains FCC ID: AXJ02532481

System is configured with IC Certification Number: 10207A-100NXRFID
or IC Certification Number: 10207A-02532480 or contains IC Certification Number 10207A-02532481

WARNING! (PART 15.21) RISK OF NON-COMPLIANCE.
Changes or modifications not expressly approved by Advanced Sterilization Products could void the user’s authority to operate the equipment. Manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment.

FCC Rules and Industry Canada (IC) Regulatory Information

Compliance Statement (Part 15.19)

The equipment device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received including interference that may cause undesired operation.

Compliance Statement (Part 15.105(b))

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Class A digital device notice “CAN ICES-3 (A)/NMB-3(A)”

RF Radiation Exposure Statement

This equipment complies with the FCC/IC radiation exposure limits set forth for portable transmitting devices operation in a controlled environment. End users must follow the specific operating instructions to satisfy RF exposure compliance.

The equipment should only be used where there is normally at least 20cm separation between the antenna and all person/user.

This transmitter must not be co-located or operation in conjunction with any other antenna or transmitter.

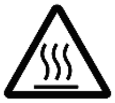
Any changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate this equipment.

Warnings, Cautions, and Notes

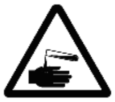
△ Warnings and cautions are accompanied by symbols surrounded by a triangle or a square and are printed in the text in bold. Warnings indicate events or conditions that can result in serious injury or death. Cautions indicate events or conditions that can result in severe damage to the equipment.

✓ Notes are printed in italics and have a checkmark in front of the word “Note.” Notes highlight specific information about the proper use and maintenance of the sterilizer.

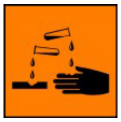
Symbols



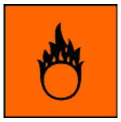
Hot surfaces present.
Do not touch without protection.



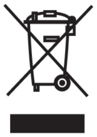
Hazardous chemical present.
Use personal protective equipment.



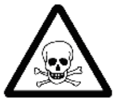
Corrosive chemical present.
Use personal protective equipment.



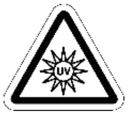
Oxidizing chemical present.
Avoid exposure, contact, or ingestion.
Use personal protective equipment.



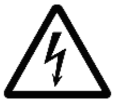
WEEE Symbol



Toxic chemical present.
Avoid exposure, contact, or ingestion.



Ultraviolet (UV) light hazard.
Do not look at the light without UV eye protection.



High voltage hazard.

I/O On/Off.

∿ Alternating current.

Chapter 3.

Load Preparation

The STERRAD® 100NX® Sterilizer is designed for sterilization of both metal and nonmetal medical devices at low temperatures. The STERRAD® sterilization process is a multiphase sterilization process that utilizes a combination of exposure to hydrogen peroxide vapor and plasma to safely sterilize medical instruments and materials without leaving toxic residue. Because the cycle operates within a dry environment and at low temperatures, it is especially suitable for instruments sensitive to heat and moisture.

⚠ **CAUTION: KNOW WHAT YOU CAN PROCESS.**

Before processing items in the sterilizer, make sure you know how the STERRAD® Sterilization Process will affect the item. When constructing your load, the total weight of the load to be sterilized should not exceed the load requirements for the specific cycle. If you have questions, or if you are in doubt about the materials in your devices, contact the medical device manufacturer or your ASP Customer Representative for more information.

⚠ **CAUTION: RISK OF VIOLATION OF WARRANTY.**

Improper processing may limit our liability for damage to processed instruments. Improper processing may also void your instrument warranty.

Load Weight Requirements

The weight of the items to be sterilized must conform to the weights used for validating the sterilizer processes. These weights are listed in the following table. The weight of the load depends on the cycle selected and whether one or both shelves are used.

Cycle Type	Weight	Shelves
STANDARD Cycle	9.7 kg (21.4 lbs) total weight	1 or 2 shelves
DUO Cycle	6.0 kg (13.2 lbs) total weight	1 or 2 shelves
EXPRESS Cycle	4.9 kg (10.7 lbs) total weight	Bottom shelf only
FLEX Cycle	9.7 kg (21.4 lbs) total weight	1 or 2 shelves

STANDARD Cycle Processing

The STERRAD® 100NX® Sterilizer can sterilize instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.

Medical devices with the following materials and dimensions can be processed in the STERRAD® 100NX® Sterilizer **STANDARD cycle:**

- Single channel stainless steel lumens with an inside diameter of 0.7 mm or larger and a length of 500 mm or shorter.†

Processing Tubing

ASP has validated the processing of non-reusable polyethylene and Teflon® (polytetrafluoroethylene) medical grade tubing with the dimension and cycles listed below. (These tubing claims have not been reviewed by the Food and Drug Administration (FDA) as the FDA does not classify tubing as medical devices.):

- An inside diameter of 1 mm or larger and a length of 1000 mm or shorter can be processed in the STERRAD® 100NX® Sterilizer **STANDARD cycle**.*

DUO Cycle Processing

Medical devices, including many flexible endoscopes with accessory devices such as light cords and cameras with the following material and dimensions can be processed in the STERRAD® 100NX® **DUO** Cycle.

- Single channel polyethylene and Teflon® (polytetrafluoroethylene) flexible endoscopes with an inside diameter of 1 mm or larger and a length of 875 mm or shorter.
- Cameras.
- Accessory light cords.
- Flexible endoscopes without lumens.

✓ ***Note:*** *Do not include more than 2 flexible endoscopes per load.*

---

†The validation testing for this lumen size was conducted using a maximum of 10 lumens in the USA; 40 lumens for markets outside the USA. Your loads should not exceed the validated maximum number of lumens.

*Sterilize without any additional load. Up to 20 pieces of tubing may be sterilized at one time.

EXPRESS Cycle Processing

The following types of medical devices can be sterilized in the **EXPRESS** Cycle:

- General medical devices requiring surface sterilization, or sterilization of mated titanium and stainless steel surfaces.
- Rigid or semi-rigid endoscopes without lumens; for example da Vinci® endoscopes.

FLEX Cycle Processing

Medical devices, including most flexible endoscopes, with the following materials and dimensions can be processed in the STERRAD® 100NX® Sterilizer **FLEX cycle:**

- Single channel polyethylene and Teflon® (polytetrafluoroethylene) flexible endoscope with an inside diameter of 1 mm or larger and length of 850 mm or shorter.**
- Flexible endoscopes without lumens.

> ✓ ***Note:*** *Do Not process more than 2 flexible endoscope per load.*

Check the medical device manufacturer's instructions before loading any item into the STERRAD® 100NX® Sterilizer.

**One or two flexible endoscopes can be processed per sterilization cycle. No additional load.

Cycles and Materials Processing

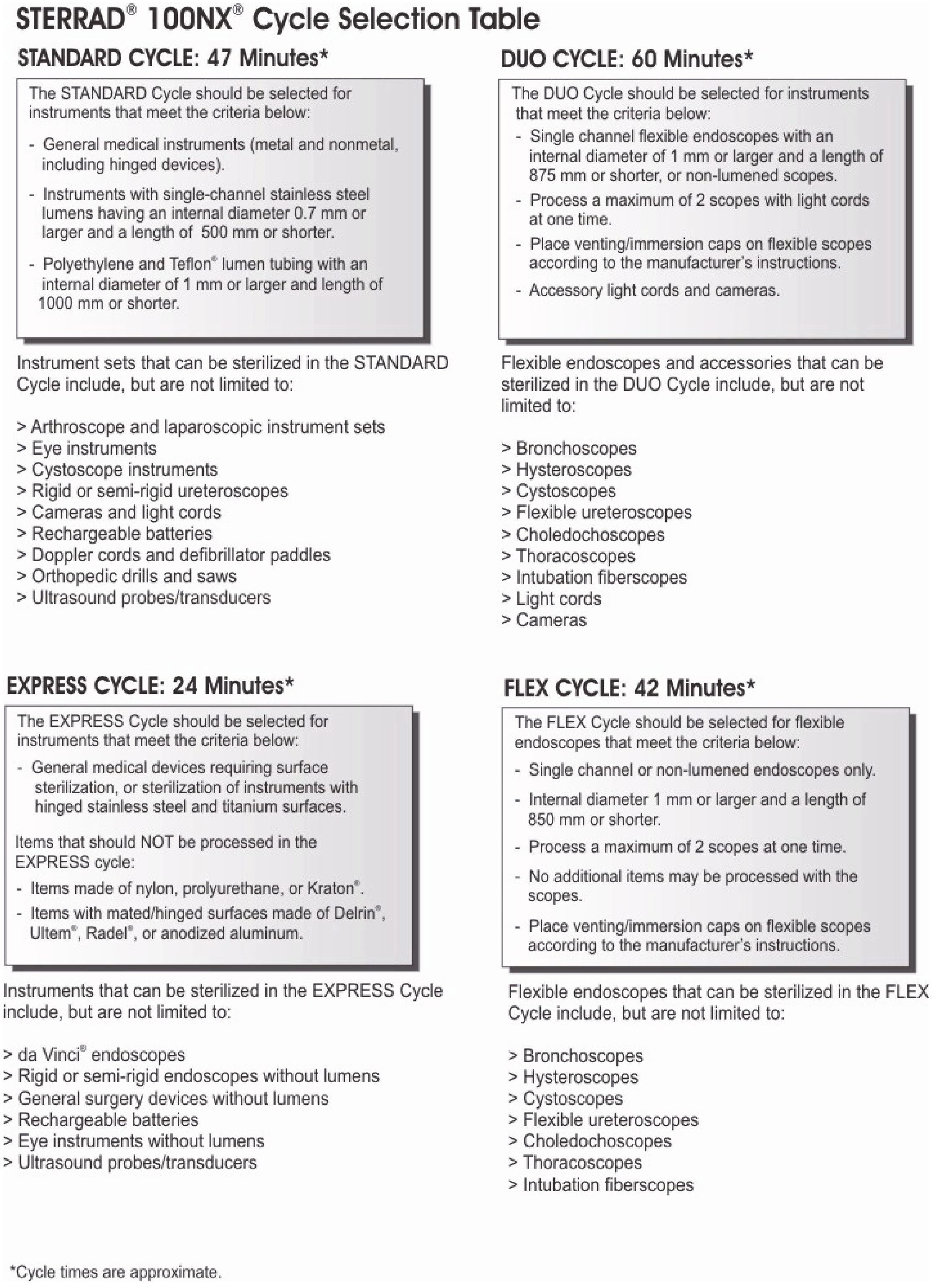
CAUTION: RISK OF DAMAGE TO LOAD OR STERILIZER.

Do not attempt to sterilize items or materials that do not comply with the guidelines specified in this user's guide. Consult the medical device manufacturer's instructions or call your ASP Representative to determine if an item can be sterilized by the STERRAD® 100NX® Sterilization System.

This chapter includes cycle information regarding recommended items, materials, and some typical devices that can be sterilized in each of the cycles on the STERRAD® 100NX® Sterilizer. Please refer to these pages whenever you need materials information.

Check the medical device manufacturer's instructions before loading any item into the STERRAD® 100NX® Sterilizer.

There is a wide variety of materials and devices that can be sterilized in the STERRAD® 100NX® Sterilizer. For more information contact your local ASP Representative or visit our website at www.aspjj.com. Information may also be obtained from the device manufacturer.



STERRAD® 100NX® Cycle Selection Table

STANDARD CYCLE: 47 Minutes*

The STANDARD Cycle should be selected for instruments that meet the criteria below:

- General medical instruments (metal and nonmetal, including hinged devices).
- Instruments with single-channel stainless steel lumens having an internal diameter 0.7 mm or larger and a length of 500 mm or shorter.
- Polyethylene and Teflon® lumen tubing with an internal diameter of 1 mm or larger and length of 1000 mm or shorter.

Instrument sets that can be sterilized in the STANDARD Cycle include, but are not limited to:

> Arthroscope and laparoscopic instrument sets
> Eye instruments
> Cystoscope instruments
> Rigid or semi-rigid ureteroscopes
> Cameras and light cords
> Rechargeable batteries
> Doppler cords and defibrillator paddles
> Orthopedic drills and saws
> Ultrasound probes/transducers

DUO CYCLE: 60 Minutes*

The DUO Cycle should be selected for instruments that meet the criteria below:

- Single channel flexible endoscopes with an internal diameter of 1 mm or larger and a length of 875 mm or shorter, or non-lumened scopes.
- Process a maximum of 2 scopes with light cords at one time.
- Place venting/immersion caps on flexible scopes according to the manufacturer's instructions.
- Accessory light cords and cameras.

Flexible endoscopes and accessories that can be sterilized in the DUO Cycle include, but are not limited to:

> Bronchoscopes
> Hysteroscopes
> Cystoscopes
> Flexible ureteroscopes
> Choledochoscopes
> Thoracoscopes
> Intubation fiberscopes
> Light cords
> Cameras

EXPRESS CYCLE: 24 Minutes*

The EXPRESS Cycle should be selected for instruments that meet the criteria below:

- General medical devices requiring surface sterilization, or sterilization of instruments with hinged stainless steel and titanium surfaces.

Items that should NOT be processed in the EXPRESS cycle:

- Items made of nylon, prolyurethane, or Kraton®.
- Items with mated/hinged surfaces made of Delrin®, Ultem®, Radel®, or anodized aluminum.

Instruments that can be sterilized in the EXPRESS Cycle include, but are not limited to:

> da Vinci® endoscopes
> Rigid or semi-rigid endoscopes without lumens
> General surgery devices without lumens
> Rechargeable batteries
> Eye instruments without lumens
> Ultrasound probes/transducers

FLEX CYCLE: 42 Minutes*

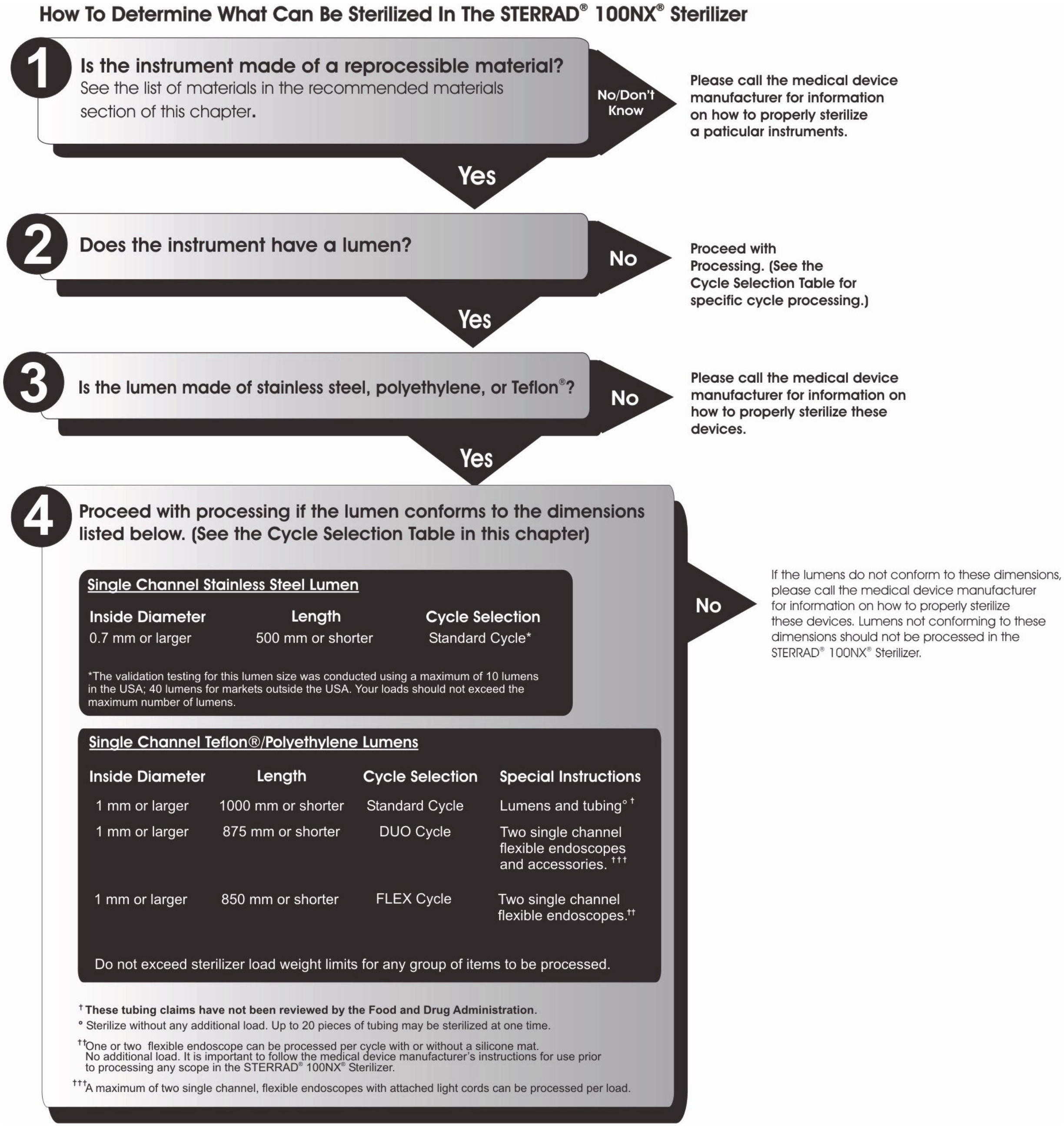
The FLEX Cycle should be selected for flexible endoscopes that meet the criteria below:

- Single channel or non-lumened endoscopes only.
- Internal diameter 1 mm or larger and a length of 850 mm or shorter.
- Process a maximum of 2 scopes at one time.
- No additional items may be processed with the scopes.
- Place venting/immersion caps on flexible scopes according to the manufacturer's instructions.

Flexible endoscopes that can be sterilized in the FLEX Cycle include, but are not limited to:

> Bronchoscopes
> Hysteroscopes
> Cystoscopes
> Flexible ureteroscopes
> Choledochoscopes
> Thoracoscopes
> Intubation fiberscopes

*Cycle times are approximate.



How To Determine What Can Be Sterilized In The STERRAD® 100NX® Sterilizer

1 Is the instrument made of a reprocessible material?
See the list of materials in the recommended materials section of this chapter.

Please call the medical device manufacturer for information on how to properly sterilize a paticular instruments.

Yes

2 Does the instrument have a lumen?

Proceed with Processing. (See the Cycle Selection Table for specific cycle processing.)

Yes

3 Is the lumen made of stainless steel, polyethylene, or Teflon®?

Please call the medical device manufacturer for information on how to properly sterilize these devices.

Yes

4 Proceed with processing if the lumen conforms to the dimensions listed below. (See the Cycle Selection Table in this chapter)

Single Channel Stainless Steel Lumen

Inside Diameter	Length	Cycle Selection
0.7 mm or larger	500 mm or shorter	Standard Cycle*

*The validation testing for this lumen size was conducted using a maximum of 10 lumens in the USA; 40 lumens for markets outside the USA. Your loads should not exceed the maximum number of lumens.

Single Channel Teflon®/Polyethylene Lumens

Inside Diameter	Length	Cycle Selection	Special Instructions
1 mm or larger	1000 mm or shorter	Standard Cycle	Lumens and tubing° †
1 mm or larger	875 mm or shorter	DUO Cycle	Two single channel flexible endoscopes and accessories. †††
1 mm or larger	850 mm or shorter	FLEX Cycle	Two single channel flexible endoscopes.††

Do not exceed sterilizer load weight limits for any group of items to be processed.

If the lumens do not conform to these dimensions, please call the medical device manufacturer for information on how to properly sterilize these devices. Lumens not conforming to these dimensions should not be processed in the STERRAD® 100NX® Sterilizer.

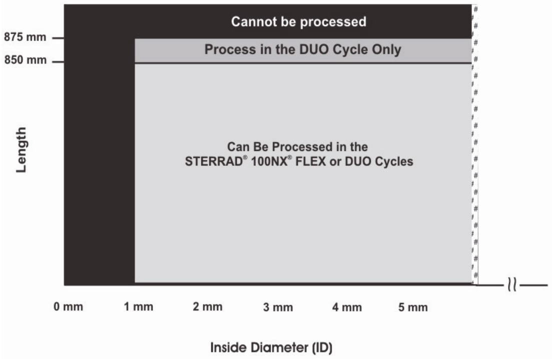
† **These tubing claims have not been reviewed by the Food and Drug Administration.**

° Sterilize without any additional load. Up to 20 pieces of tubing may be sterilized at one time.

†† One or two flexible endoscope can be processed per cycle with or without a silicone mat. No additional load. It is important to follow the medical device manufacturer's instructions for use prior to processing any scope in the STERRAD® 100NX® Sterilizer.

††† A maximum of two single channel, flexible endoscopes with attached light cords can be processed per load.

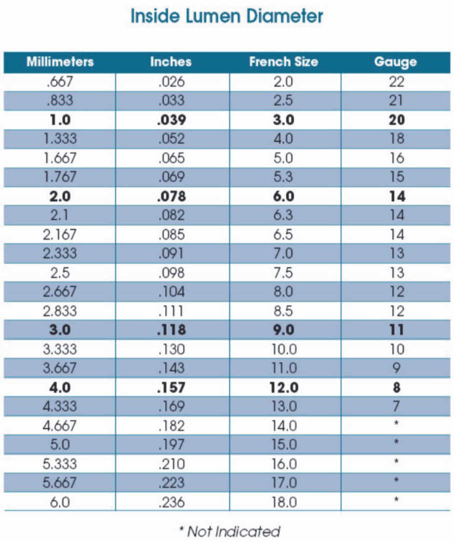
Processing Single-Channel Flexible Endoscopes With Polyethylene and Teflon® Lumens Only In The STERRAD® 100NX® Sterilizer*



*One or two single-channel flexible endoscope can be processed per cycle with or without a silicone mat. No additional load (Flex Only).

It is important to follow the medical device manufacturer's instructions for use prior to processing any scope in the STERRAD® 100NX® Sterilizer.

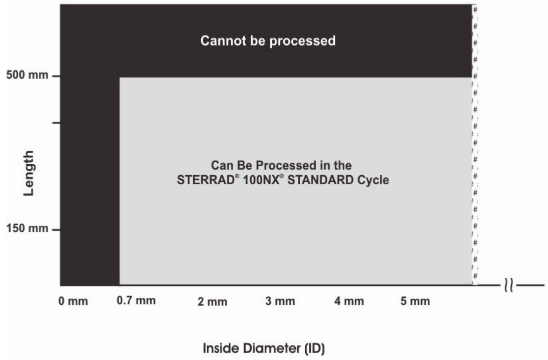
Inside Lumen Diameter



Millimeters	Inches	French Size	Gauge
.667	.026	2.0	22
.833	.033	2.5	21
1.0	**.039**	**3.0**	**20**
1.333	.052	4.0	18
1.667	.065	5.0	16
1.767	.069	5.3	15
2.0	**.078**	**6.0**	**14**
2.1	.082	6.3	14
2.167	.085	6.5	14
2.333	.091	7.0	13
2.5	.098	7.5	13
2.667	.104	8.0	12
2.833	.111	8.5	12
3.0	**.118**	**9.0**	**11**
3.333	.130	10.0	10
3.667	.143	11.0	9
4.0	**.157**	**12.0**	**8**
4.333	.169	13.0	7
4.667	.182	14.0	*
5.0	.197	15.0	*
5.333	.210	16.0	*
5.667	.223	17.0	*
6.0	.236	18.0	*

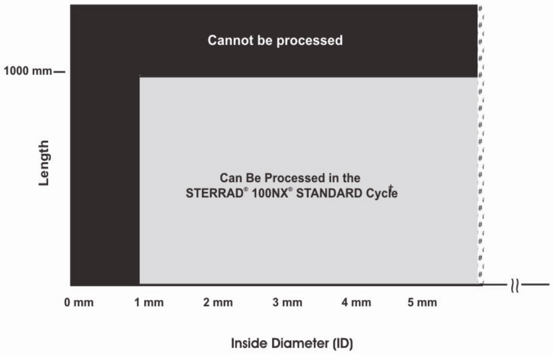
** Not Indicated*

Processing Single Channel Stainless Steel Lumens In The STERRAD® 100NX® Sterilizer*



* The validation testing for this lumen size was conducted using a maximum of 10 lumens in the USA; 40 lumens for markets outside the USA. Your loads should not exceed the validated maximum number of lumens.

Processing Polyethylene and Teflon® Lumens and Tubing In The STERRAD® 100NX® Sterilizer*



***These tubing claims have not been reviewed by the Food and Drug Administration.**

Recommended Materials

There is a wide variety of materials and devices that may be sterilized in the sterilizer. The materials listed below are commonly found in medical devices and represent typical classes of materials used to construct medical devices. The items marked with an asterisk (*) may have limited life after repeated sterilization.

Please contact your ASP Representative for more information. Information may also be obtained from the device manufacturer.

Thermoplastics

- Ethylvinyl Acetate (EVA)
- Kraton® Polymers
- Liquid Crystal Polymer (LCP)
- Polyacetal (Delrin® acetal resin)*
- Polyamide (Nylon)*
- Polycarbonate
- Polyetheretherketone (PEEK)
- Polyetherimide (ULTEM® Polymers)
- Polyethylene
- Polymethyl methacrylate (PMMA)*
- Polyphenylene sulfone (Radel®)*
- Polypropylene
- Polystyrene
- Polytetrafluoroethylene (Teflon®)

Thermoplastic Elastomers

- Santoprene™

Thermosetting Elastomers

- Silicone
- Polyurethane
- PVC

Glass

- Glass

Metal

- Aluminum
- Brass
- Gold
- Stainless steel
- Titanium

Items Not To Be Processed

- Single use items for which the manufacturer does not recommend resterilization.
- Liquids and powders.
- Items or materials that absorb liquids.
- Items made of materials that contain cellulose, such as cotton, paper or cardboard, linens, huck towels, gauze sponges, or any item containing wood pulp
- Paper instrument count sheets or lot stickers.
- Items with hinged/mated nylon surfaces.
- Instruments and devices that cannot withstand a vacuum and are labeled for gravity steam sterilization methods only.
- Items whose design permits the surfaces to collapse onto each other unless some method is used to keep the surfaces separated.
- Devices with dead-end lumens.

- Devices with internal parts, such as sealed bearings, that cannot be immersed, may present difficulties in cleaning and should not be processed in the STERRAD® 100NX® Sterilizer.
- Implants for which the manufacturer has not specifically recommended sterilization in the STERRAD® 100NX® Sterilizer.

Do Not Process in the EXPRESS Cycle

- Items made of nylon cannot be processed in the EXPRESS Cycle.
- Items made of Kraton® cannot be processed in the EXPRESS Cycle.
- Items made of Polyurethane cannot be processed in the EXPRESS Cycle.
- Items with mated Delrin® surfaces cannot be processed in the EXPRESS Cycle.
- Items with mated anodized aluminum surfaces cannot be processed in the EXPRESS Cycle.
- Items with mated Radel® surfaces cannot be processed in the EXPRESS Cycle.
- Items with mated Ultem® surfaces cannot be processed in the EXPRESS Cycle.
- Items with lumens cannot be processed in the EXPRESS Cycle.

Do Not Process in the DUO Cycle

- Items with mated anodized aluminum surfaces cannot be processed in the DUO Cycle.

Guidelines for Preparing Items to Be Sterilized

✓ ***Note:*** *All items must be cleaned, rinsed, and* ***thoroughly dried*** *before being placed in the STERRAD® 100NX® Sterilizer. Loads containing moisture may cause cycle cancellations.*

Cleaning, Rinsing, and Drying

Cleaning and sterilization are two separate processes. Proper cleaning of instruments and devices is a critical and necessary step prior to sterilization.

- All items including accessories must be thoroughly cleaned, rinsed, and dried before loading into the sterilizer.
- Carefully inspect all instruments, devices, and accessories for cleanliness and dryness prior to packaging. If visible soil is present, the item must be re-cleaned and dried prior to sterilization. If moisture is present, dry the item thoroughly prior to sterilization.
- Carefully inspect all instruments, devices, and accessories for flaws or damage prior to packaging. Items with flaws or damage should be replaced or repaired before using.

✓ ***Note:*** *Periodic careful inspection of items after repeated exposure to disinfectant/cleaner/sterilant is necessary, due to the potential damaging effects of the chemical agents.*

Cleaning is necessary to remove organic and inorganic soil and debris from equipment. This process also removes many microorganisms from the surface of the items. Sterilization then inactivates all remaining spores and live microorganisms.

- **Clean** your devices according to the medical device manufacturers' instructions. You must remove all blood, tissue, and soil from items using appropriate detergents, cleansers and/or methods.
- **Rinse** items thoroughly to remove detergent or cleanser residue. Use treated water that is of a quality that ensures hard water stains do not occur. Failure to remove all organic materials or detergents may result in the formation of light-colored residue on the devices. If residue is visible, you should clean, rinse, dry, and resterilize the device prior to use.

- **Dry all items thoroughly**. An acceptable method for drying is to blow compressed gas through the lumen until no moisture exits the distal end of the device. Please ensure that any method used to dry the devices is in accordance with the manufacturers' instructions for use or contact the device manufacturer to obtain appropriate and safe procedures. It is necessary to remove moisture from all parts of the items. Only dry items should be loaded into the sterilization chamber to prevent cycle cancellation.

WARNING! POSSIBLE RESIDUAL HYDROGEN PEROXIDE CONTACT!

Failure to ensure that instruments are completely dry before they are processed in the STERRAD® sterilizer may result in residual hydrogen peroxide being present on the surface of the load after the cycle is complete. This may cause contact burns when the surface of the load is handled.

- Some complex reusable medical devices may require disassembly for proper cleaning and sterilization. It is very important that you follow the device manufacturers' recommendations concerning cleaning and sterilization. In the absence of STERRAD® System-specific instructions, please contact the relevant medical device manufacturer.

WARNING! POSSIBLE NON-STERILE DEVICE!

Loads containing moisture may result in either a non-sterile device or cycle cancellation. Wear chemical resistant gloves when handling items from any load containing moisture.

Packaging and Loading

If you choose to package the instruments (highly recommended), proper use and preparation of trays, pouches, and instruments can minimize or prevent cycle cancellations and positive biological indicator (BI) results due to load related problems. All instruments must be cleaned, rinsed, and **thoroughly dried** before loading into the sterilizer.

Special considerations for loading and processing flexible endoscopes are presented at the end of this chapter.

Instrument Trays

- Only STERRAD® Instrument Accessories and APTIMAX® Instrument Trays, are recommended for use in the STERRAD® 100NX® Sterilizer. These instrument trays are specially designed to allow diffusion of hydrogen peroxide and plasma around every item in the load.

Tray Mats

- Instrument trays should only be padded with STERRAD® Instrument Mats or polypropylene sterilization wrap. **Never use** linen, cellulose, or any materials listed in the “Items Not To Be Processed” section.
- Follow the *Instructions for Use* included with the STERRAD® Instrument Mats to determine the number of mats that can be used at one time in the chamber. Do not use more than the recommended amount of mat material in the chamber at any time.

Cycle Name	Square Centimeters	Square Inches
STANDARD	2250	349
DUO	2774	430
FLEX	2250	349
EXPRESS	1387	215

- Do not use foam pads in instrument trays as they may absorb the hydrogen peroxide.

Packaging

- Use only STERRAD® Sterilizer-compatible polypropylene sterilization wrap and Tyvek® pouches.Tyvek® Pouches and Rolls with STERRAD® Chemical Indicators are the only pouches and rolls available on the market that are validated by ASP. They are the only pouches and rolls validated by ASP for efficacy and stability.

- Do not use paper pouches or sterilization wraps containing cellulose or cotton.
- Do not use any wraps or packaging that are not approved by ASP or materials listed in the “Items Not To Be Processed” section. In the USA, use only FDA-cleared polypropylene wraps.
- Properly arrange the items or the scope in a tray to ensure adequate diffusion of hydrogen peroxide throughout the load.
- Place peel pouches on edge, if possible. Arrange them so that the transparent side of a pouch faces the opaque side of the next pouch. Do not stack pouches on top of each other.
- Do not stack instruments inside the trays. Do not stack trays. Do not stack trays within trays. Do not wrap instruments within a wrapped tray.
- If you are using rigid containers cleared by the FDA for use in the STERRAD® 100NX® Sterilizer, follow the Instructions for Use provided by the rigid container manufacturer. Verify that the rigid containers are cleared for use in each sterilization cycle. Remember the following:
    - Do not stack instruments inside the containers.
    - Do not stack containers.
    - Do not stack containers within containers.
    - Do not wrap instruments within the containers.
- Place STERRAD® Chemical Indicator Strips inside trays and pouches as needed.

Loading

- Do not allow any item to touch the walls of the sterilization chamber, door, or electrode.

STANDARD and FLEX Cycles Loading Preparation

- The STERRAD® 100NX® Sterilizer **STANDARD** and **FLEX** Cycles were validated using a load weight of 4.9 kg (10.7 lbs) per shelf. When constructing your load, the total weight of the load to be sterilized should not exceed 9.7 kg (21.4 lbs).

DUO Cycle Loading Preparation

- The STERRAD® 100NX® Sterilizer **DUO** Cycle was validated using a total load weight of 6.0 kg (13.2 lbs). When constructing your load, the total weight of the load to be sterilized should not exceed 6.0 kg (13.2 lbs).

EXPRESS Cycle Loading Preparation

- The STERRAD® 100NX® Sterilizer **EXPRESS** Cycle was validated using a load weight of 4.9 kg (10.7 lbs) on the bottom shelf only. When constructing your load, the total weight of the load to be sterilized should not exceed 4.9 kg (10.7 lbs).

CAUTION: RISK OF DAMAGE TO LOAD OR STERILIZER.

Do not allow metal objects to come into contact with the walls of the chamber, door, or electrode. Contact with the walls, door, or electrode can cause a cycle cancellation, and/or damage the item or the sterilizer. Provide at least 25 mm (1 inch) of space between the load and the electrode.

Chemical Indicators

STERRAD® Chemical Indicator Strips and STERRAD® SEALSURE® Chemical Indicator Tape offer a method to verify that the load has been exposed to hydrogen peroxide in the sterilizer. Chemical indicators are not a substitute for biological indicators. If you use chemical indicator strips or chemical indicator tape, follow the *Instructions for Use* that accompany these items as you prepare the load.

- Place STERRAD® Chemical Indicator Strips inside trays and Tyvek® pouches or follow your health care facility's procedures.
- Secure all wraps with STERRAD® SEALSURE® Chemical Indicator Tape.
- Do not use chemical indicators or tape designed for other sterilization processes.

Special Considerations for Flexible Endoscopes

Flexible endoscopes are sensitive and complex medical instruments. Read the flexible endoscope manufacturer's instructions for each endoscope before preparation and loading into the sterilizer. Take special care to confirm that venting caps are placed according to the manufacturer's instructions. Venting caps are intended to prevent damage to scopes that are being exposed to a vacuum, regardless of the sterilant used.

In addition, if you are processing a flexible endoscope containing a water resistant "immersion" cap, you *must remove* the immersion cap prior to processing. If the immersion cap is not removed prior to processing, it will damage the scope due to the inability to properly vent.

FLEX Cycle: A maximum of 2 flexible endoscopes can be processed per load, with or without silicone mats. Do not add any additional items to the load.

DUO Cycle: A maximum of 2 flexible endoscopes can be processed per load, with or without silicone mats. You can also process 1 flexible endoscope with its light cord and a camera.

CAUTION: RISK OF DAMAGE TO LOAD.

Prior to processing flexible endoscopes in the STERRAD® 100NX® Sterilizer, please contact the medical device manufacturer, or your ASP Customer Representative.

Chapter 4.

Operation

Before You Start

Each time you use the STERRAD® 100NX® Sterilizer, follow the instructions provided in the “Load Preparation” chapter. It is your responsibility to be familiar with the load preparation and safety information provided in this user’s guide.

Start and Warm-up

1. Turn on the main power switch located on left front side panel (as you face it) of the sterilizer.
2. The sterilizer begins by warming up. The warm-up can take up to 1 hour.

   ✓ ***Note:*** *The sterilizer should not be turned off during warm-up.*

3. “Touch Screen to Start” appears on the display when the sterilizer is ready for use.

Biological Indicators

Biological indicators are an important method of confirming that sterilization was achieved during a cycle. The following biological testing methods are recommended:

- The STERRAD® CYCLESURE® 24 Biological Indicator (BI), when used as a standard method for frequent monitoring of the STERRAD® Sterilizer cycle, are used as follows:

  Compare the processed STERRAD® CYCLESURE® 24 vial with the positive control vial.

1. The absence of a color change and turbidity in the processed STERRAD® CYCLESURE® 24 vial (i.e. the media remains purple as compared directly to a negative control) indicates that the sterilization conditions were achieved in the STERRAD® Sterilizer (sufficient to kill at least one million of the most resistant identified bacterial spores).
2. If the processed STERRAD® CYCLESURE® 24 BI changes color from purple to yellow (as in the positive control vial), and/or exhibits turbidity, this indicates that conditions necessary to achieve sterilization in the STERRAD® Sterilizer have not been met.

   In addition, inspect the chemical indicator response for the correct color change and verify “Cycle Status: Passed” and “Process Complete” from the cycle completion report.

- Use of the STERRAD® CYCLESURE® 24 Biological Indicator (BI) in a test pack configuration for periodic testing (i.e. performance qualification upon installation and revalidation) confirms that a sterility assurance level (SAL) of 10^{-6} has been achieved during the cycle. Verify “Cycle Status: Passed” and “Process Complete from the cycle completion report.

  Note: Instructions for use are provided in the test pack.

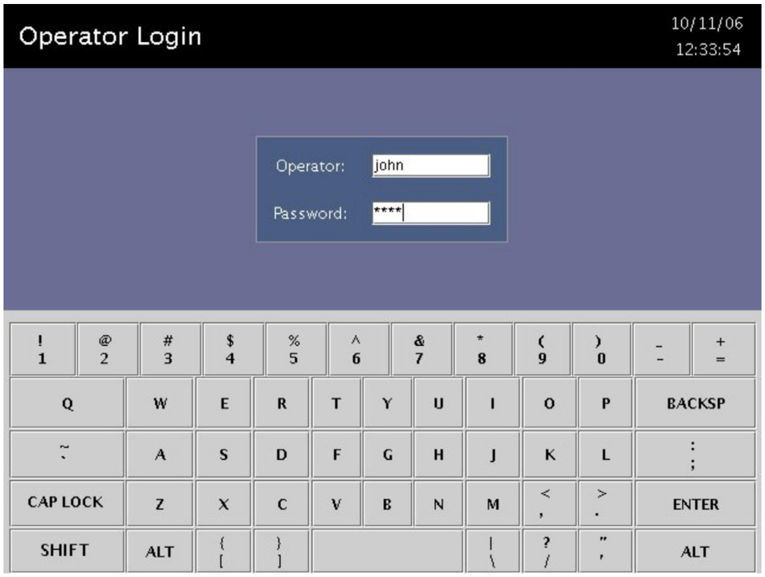
Place a STERRAD® CYCLESURE® 24 BI in the chamber at the back of the bottom shelf. Biological testing should be performed at least once per day or as specified by your health care facility’s policy. Review the *Instructions for Use* included with the biological indicator to ensure its proper use.

For the STERRAD® 100NX® DUO cycle in the United States, the STERRAD® CYCLESURE® 24 BI should only be used in a test pack configuration.

Login

✓ **Note:** *If your sterilizer has been configured not to require operator login, the login screen will not appear. Skip to the subsection titled Entering Load Information.*

When you touch the “Touch Screen to Start” screen, the sterilizer displays the Operator Login screen.



Operator Login

10/11/06
12:33:54

Operator: john

Password: ****

! 1 @ 2 # 3 $ 4 % 5 ^ 6 & 7 * 8 (9) 0 _ - + =
Q W E R T Y U I O P BACKSP
~ ` A S D F G H J K L : ;
CAP LOCK Z X C V B N M < , > . ENTER
SHIFT ALT { [}] | \ ? / " ' ALT

Figure 1. Operator Login Screen.

1. Touch the **Operator** field. The cursor appears in the field.

   ✓ ***Note:*** *Operator and Password fields are case-sensitive.*

2. Use the on-screen keyboard to type your assigned operator identification.
3. Touch the **ENTER** key. The cursor jumps to the **Password** field.
4. Type your password. The screen displays a series of "*" characters in place of the characters you type. This is done to keep others from reading your password.
5. When you have finished entering your password, touch the **ENTER** key.

Entering Load Information

✓ ***Note:*** *If your sterilizer has been configured not to require load item data, this screen will not appear. Skip to the subsection titled Cycle Notes.*

Enter Load Item Data

The Load Item Data screen allows you to enter information about the contents of the load. This can be done for tracking and traceability or may be useful for inventory purposes.

Items can be typed into the screen or selected from a predefined list of items. This information is stored and printed on a cycle report. It can also be transferred to a host computer over a network connection.

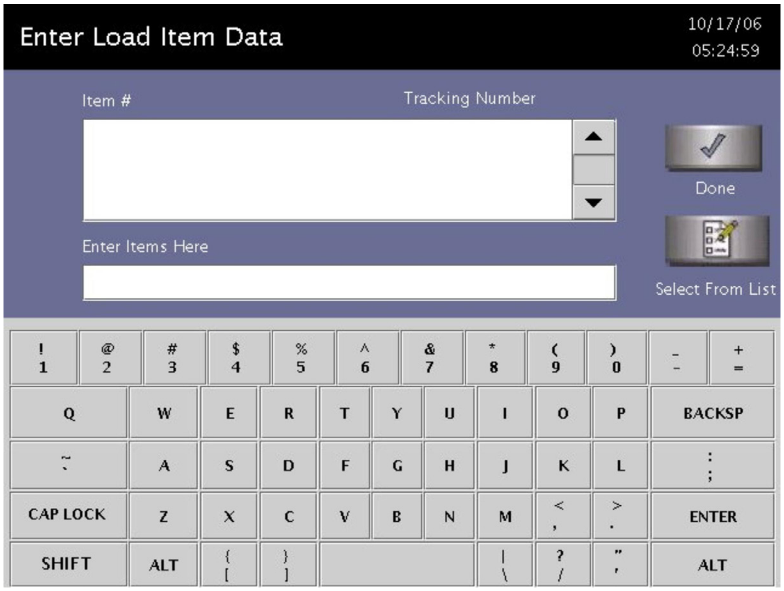

Enter Load Item Data
10/17/06
05:24:59
Item #
Tracking Number
Done
Enter Items Here
Select From List
! 1 @ 2 # 3 $ 4 % 5 ^ 6 & 7 * 8 (9) 0 _ - + =
Q W E R T Y U I O P BACKSP
~ ` A S D F G H J K L : ;
CAP LOCK Z X C V B N M < , > . ENTER
SHIFT ALT { [}] | \ ? / " ' ALT

Figure 2. Enter Load Item Data.

1. To enter items not in the database, type the item information in the “Enter Items Here” field. Touch **ENTER** to accept the item. Repeat for additional items always touching **ENTER** after each item. Touch **Done** when the list is complete.
2. An optional barcode scanner can be used to enter load item data. You may use this feature if your sterilizer is equipped with this option.

Select From List

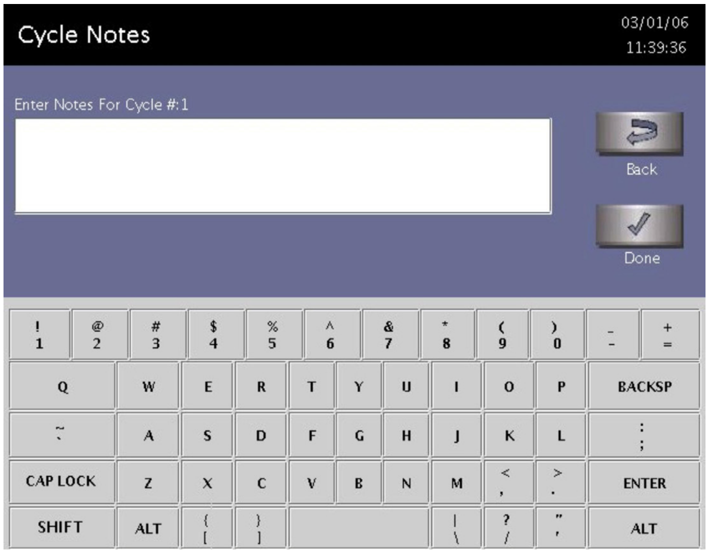
If a database has been established containing frequently used load information, you can select that information using the following steps:

1. Touch **Select From List.**
2. Scroll up or down the load item menu list to the desired item.
3. Touch the items you wish to add to your current list and touch **Select.**
4. Touch **Done** to complete the list.
5. Touch **Keyboard** to return to the keyboard entry fields or to use a barcode scanner.

Cycle Notes

✓ ***Note:*** *If your sterilizer has been configured not to require cycle notes, this screen will not appear.*

The Cycle Notes screen allows you to enter information about the cycle. For example; record information about biological indicators used in the cycle or other information that should be stored in the cycle history file. This information is printed on the cycle report, and can be transferred to a host computer over a network connection.



Cycle Notes

03/01/06
11:39:36

Enter Notes For Cycle #:1

Back
Done
! 1
@ 2
# 3
$ 4
% 5
^ 6
& 7
* 8
(9
) 0
_ -
+ =
Q W E R T Y U I O P BACKSP
~ ` A S D F G H J K L : ;
CAP LOCK Z X C V B N M < , > . ENTER
SHIFT ALT { [}] | \ ? / " ' ALT

Figure 3. Cycle Notes.

1. Touch the **Enter Notes for Cycle** field. The cursor appears in the field.
2. Use the on-screen keyboard to type your notes.
3. When data entry is complete, touch the **Done** button.
4. If conditions exist which prevent a sterilization cycle from starting; e.g., no cassette, hydrogen peroxide monitor is blocked, etc., a message is displayed on the screen.
5. The program displays the **System Ready** screen.
6. Touch **Back** to return to the previous screen.

Loading the Chamber

✓ ***Note:*** *The door is equipped with a safety mechanism that prevents it from closing if it encounters an obstruction. If this occurs, the door stops immediately. You must use the touch screen to open the door.*

1. Open the active chamber door by pressing the Open Door foot pad, or by touching **Open Door** on the display, and place your load on the shelves.

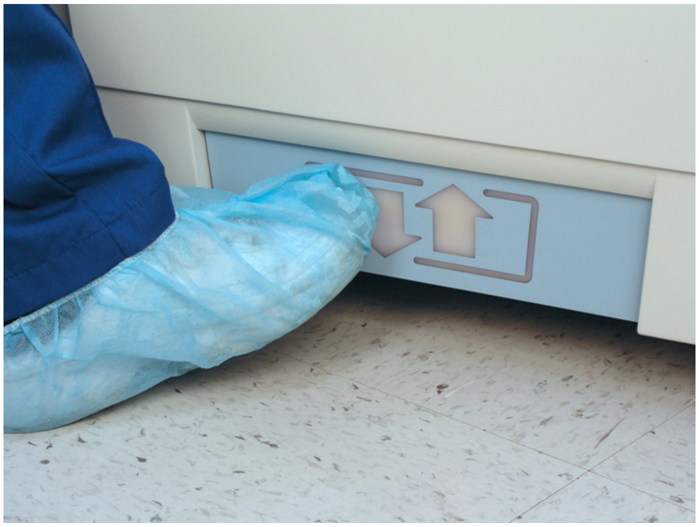


Figure 4. Touch the Foot Pad to Open the door.

✓ ***Note:*** *If necessary, the top shelf can be removed to accommodate a large load placed on the bottom shelf.*

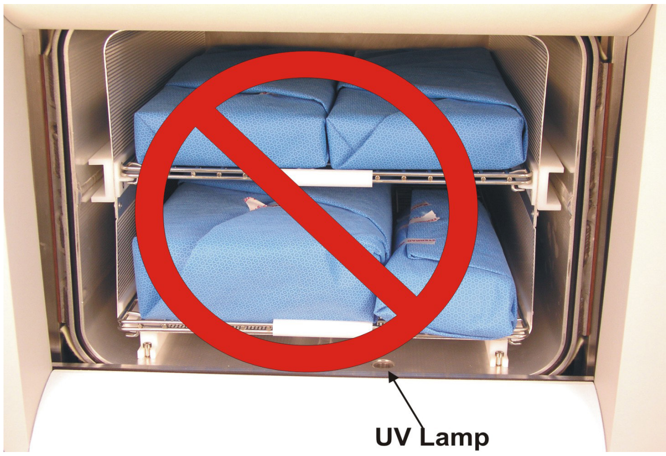


Figure 5. Do Not Block the UV Lamp.

2. When placing the load on the shelves, make certain that you do not block the ultraviolet lamp beam in the front right (your right) side of the chamber. Make sure the load is centered on the shelves and that the shelves are centered in the chamber.

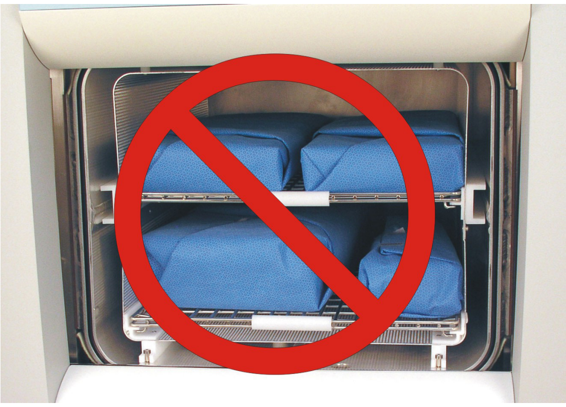


Figure 6. The Load Should NOT Touch the Electrode.

3. Do not allow any part of the load to touch the electrode, the back wall of the chamber, or the inside of the door.
4. Leave at least 1 inch (25 mm) of free space between the load and the electrode to allow hydrogen peroxide to diffuse around the load.

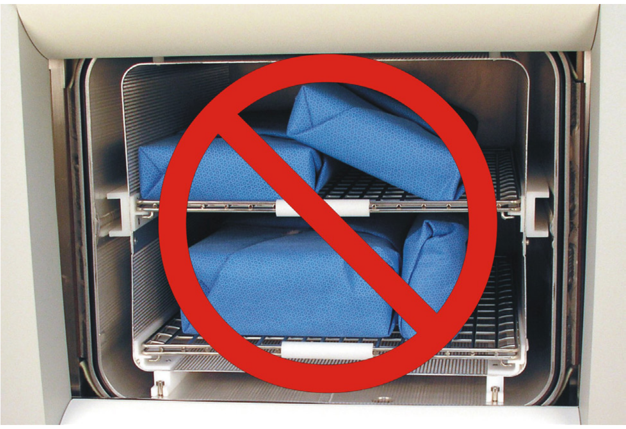


Figure 7. Do NOT Stack Trays.

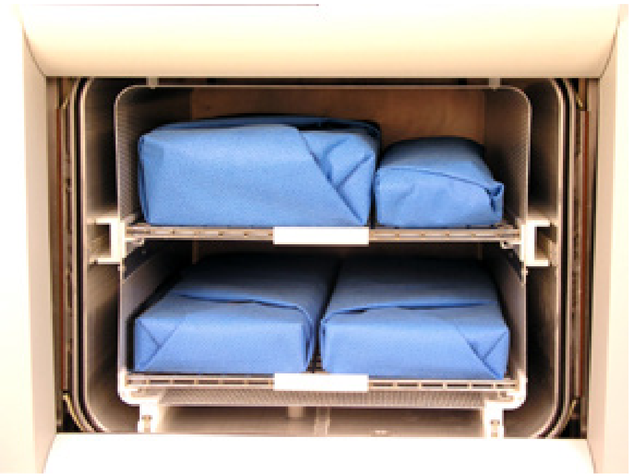


Figure 8. Load Correctly Placed for STANDARD Cycle Processing.

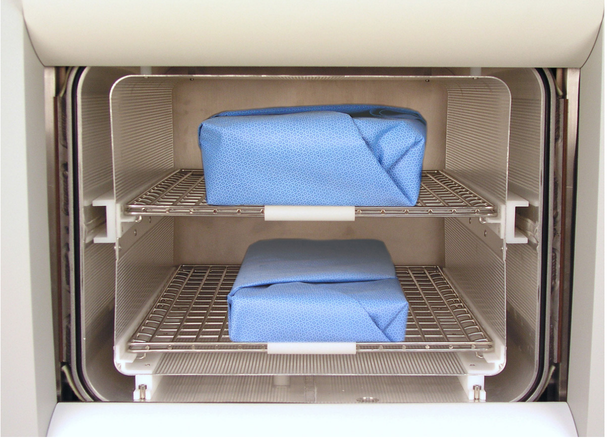


Figure 9. Load Correctly Placed for DUO and FLEX Cycle Processing.

5. When you are finished loading the chamber, close the door by tapping the foot pad or pressing the **Close Door** button on the touch screen.
6. If a message requesting that the door be closed is displayed, the door is not securely closed. Make certain that nothing is caught in the door seal.

Loading Requirements for the EXPRESS Cycle

Only the bottom shelf of the STERRAD® 100NX® Sterilizer should be used when processing loads in the EXPRESS Cycle. The following figure shows a correctly placed load.

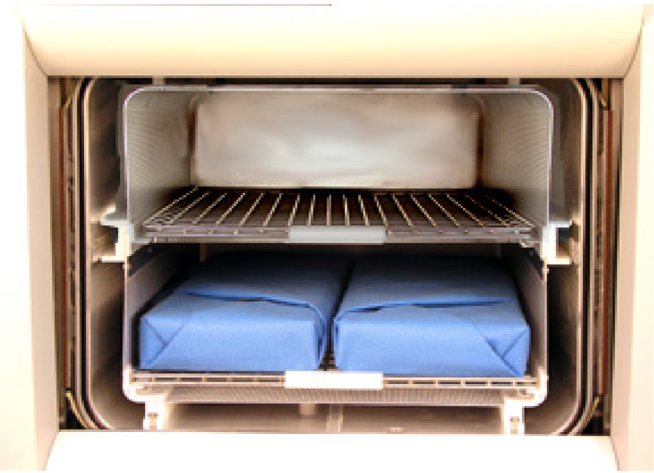
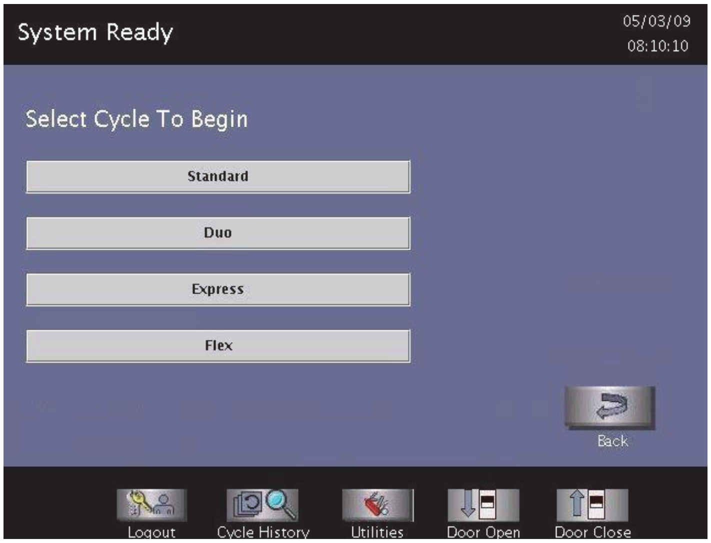


Figure 10. Load Correctly Placed for EXPRESS Cycle Processing.

Selecting and Starting a Cycle

When the load has been placed in the chamber, and the door has been closed, use the System Ready screen to start the cycle. The following display shows all the cycles available for the STERRAD® 100NX® Sterilizer. You may have one or more cycles installed and enabled on your system. Make sure you understand the differences in the cycles and what types of materials can be sterilized in each cycle



System Ready

05/03/09
08:10:10

Select Cycle To Begin

Figure 11. Touch the Screen to Start Your Cycle.

The screen displays the message “Please Insert New Cassette” if a new cassette is required, if the cassette in the sterilizer is expired, or if there is no cassette installed in the sterilizer. Follow the instructions in the next section to insert a new cassette.

Touch your choice of cycle from those displayed and then touch confirm to start the cycle; the cycle starts.

✓ ***Note:*** *When alternating between cycle types, the system needs a few minutes to adjust. This adjustment period does not apply when processing consecutive STANDARD and FLEX, or DUO and EXPRESS Cycles.*

✓ ***Note:*** *If a cycle installed on your system does not appear on the cycle selection screen, this cycle may have been disabled by the supervisor. See Supervisor Level information to learn how to enable/disable an installed cycle.*

System Ready Screen

The System Ready screen displays a number of buttons allowing you to select cycles based on the cycles that are loaded and enabled on your sterilizer.

Cycle Types

- **STANDARD** cycle sterilizes the load in about 47 minutes. This cycle is installed on all systems.
- **DUO** cycle is for sterilization of flexible endoscopes with their light cords and cameras.It sterilizes the load in about 60 minutes.
- **FLEX** cycle is specifically designed for flexible endoscopes and sterilizes the load in about 42 minutes.
- **EXPRESS** cycle is for surface sterilization of general medical devices, rigid and semi-rigid endoscopes without lumens; and sterilization of mated stainless steel and titanium devices. It sterilizations the load in about 24 minutes.

Functions

- **Logout** is used when the current operator is finished using the sterilizer and the option is enabled. When **Logout** is selected, you must re-login to use the sterilizer.
- **Cycle History** displays the Select Cycle History screen. This screen allows you to select a cycle history file and view or print it.
- **Utilities** are available only to operators with Supervisor-level access.
- It displays the Additional Utilities Menu.
- **Door Open** opens the active door.
- **Door Close** closes the active door.

Inserting a Cassette

1. Take a new STERRAD® 100NX® Cassette out of the shipping carton.

✓ ***Note:*** *Always wear chemical resistant latex, PVC (vinyl), or nitrile gloves when handling a cassette.*

2. Look at the package carefully before opening it. The indicator strip should be white. **If the indicator strip is red, or if you see droplets of moisture, do not open the package** – it is possible that hydrogen peroxide has leaked inside the package. Refer to the cassette *Instructions for Use* for proper handling instructions.
3. If the indicator strip is white, open the cassette package.

4. Position the cassette so that the arrows are pointing straight into the cassette door slot of the sterilizer. Do not insert the cassette at an angle.

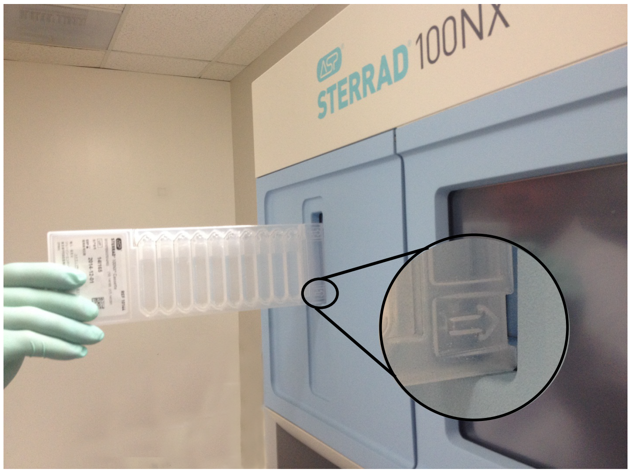


Figure 12a. Inserting the Cassette into the Slot.

5. Completely insert the cassette into the cassette slot until it reaches a stop, the cassette must be flushed with the panel.
6. After a slight pause, the system will complete the cassette insertion automatically. Do not use excessive force to insert the cassette.

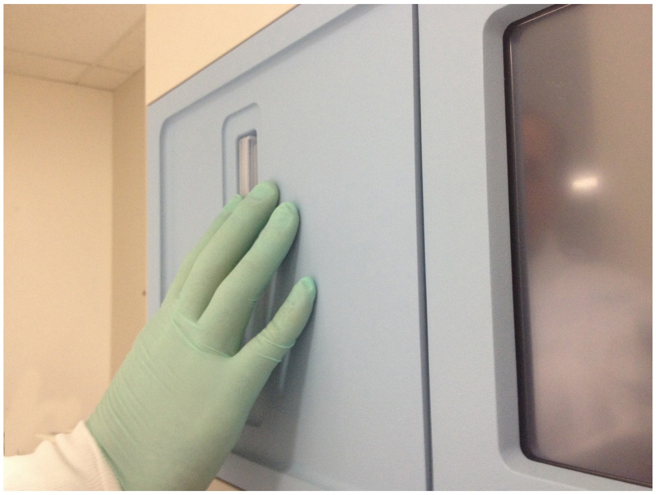
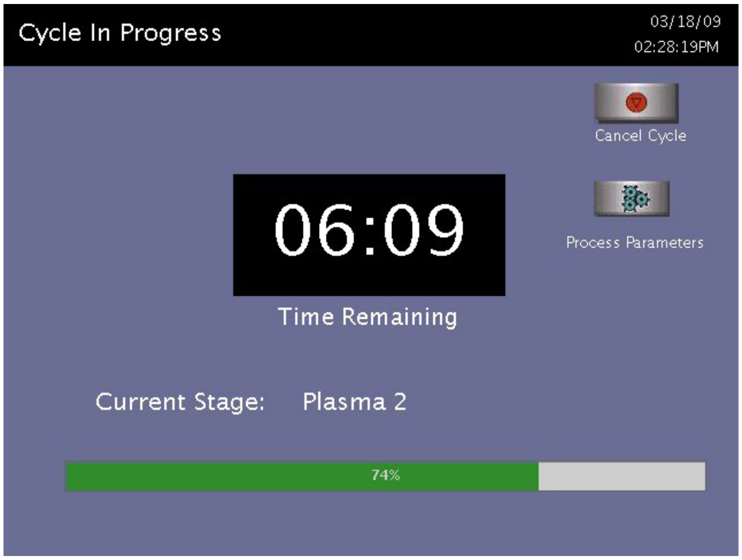


Figure 12b. Inserting the Cassette into the Slot.

Cycle in Progress

When you touch the **Start Cycle** button (after selecting the cycle type), the sterilizer starts a “countdown clock” and begins the sterilization cycle.



Cycle In Progress

03/18/09
02:28:19PM

06:09

Time Remaining

Current Stage: Plasma 2

Figure 13. Cycle In Progress. The Countdown Clock is Displayed.

The clock displays the estimated number of minutes and seconds remaining before the cycle is finished. The “Time Remaining” field updates as the sterilization cycle progresses. As each sterilization cycle stage runs, the screen displays the name of the stage. A moving bar graph also displays the percent of the cycle that is complete. For details about the current stage information, refer to the printouts in the “Reports and Files” chapter.

Canceling a Cycle

There may be occasions when it is necessary to cancel a cycle before it is completed.

To cancel a cycle, do the following:

1. Touch the **Cancel Cycle** button. The screen displays a confirmation message.

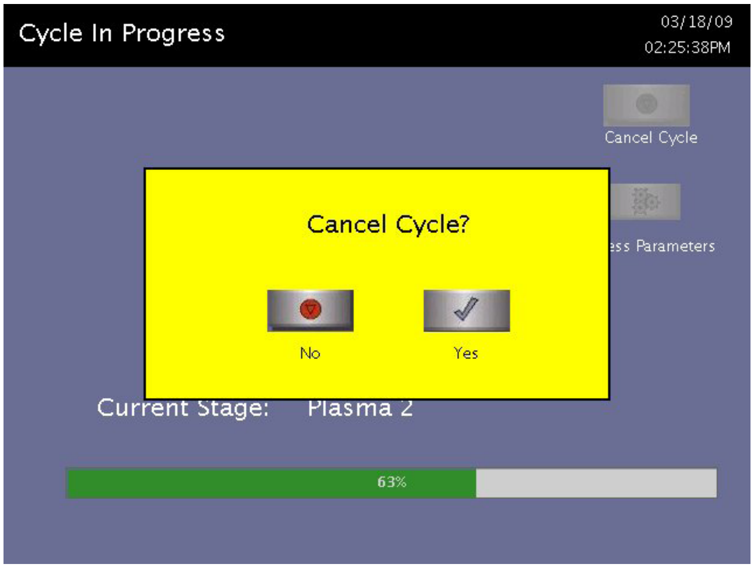

Cycle In Progress
03/18/09
02:25:38PM
Cancel Cycle
ess Parameters
Cancel Cycle?
No
Yes
Current Stage: Plasma 2
63%

Figure 14. Cancel Cycle Confirmation. Touch Yes or No.

2. Touch No to continue with the cycle. Touch Yes to cancel the cycle. Once the cycle cancellation sequence begins, the screen turns red and the cancellation sequence cannot be interrupted. The cancellation sequence may take up to ten minutes to complete.

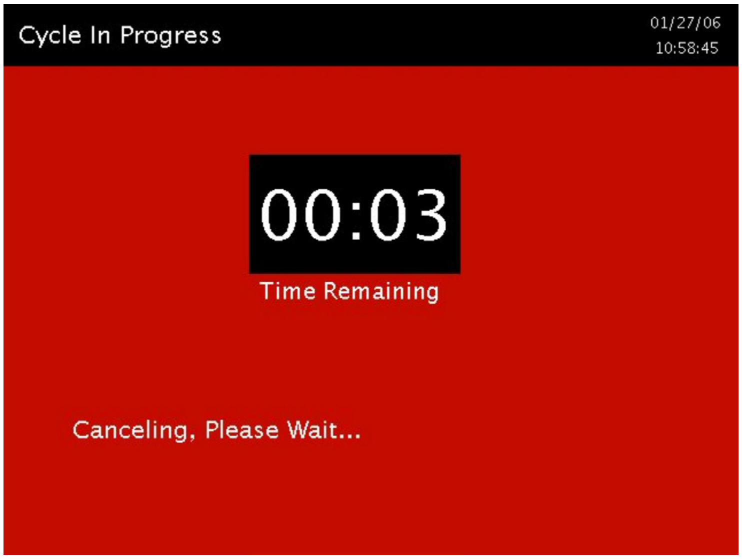

Cycle In Progress
01/27/06
10:58:45
00:03
Time Remaining
Canceling, Please Wait...

Figure 15. Cycle Cancellation In Progress. Cancellation Has Been Confirmed.

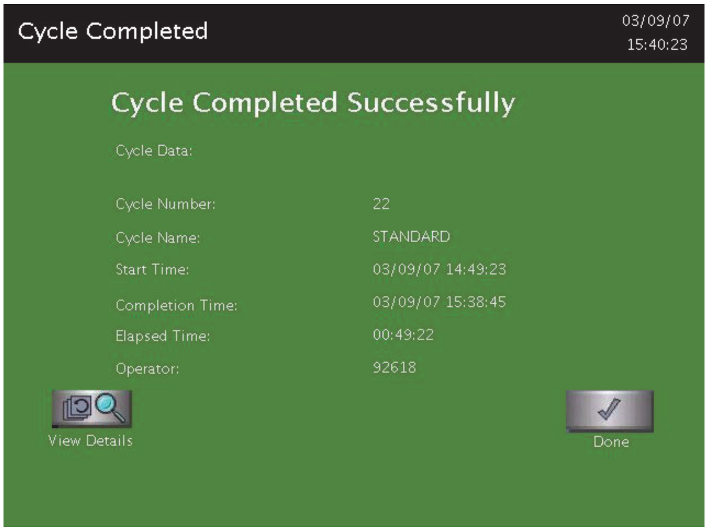
Loads from canceled cycles should be rewrapped using new packaging materials, STERRAD® Chemical Indicator Strips, and STERRAD® SEALSURE® Chemical Indicator Tape. If a biological indicator was used in the canceled load, the previously used biological indicator must be discarded and a new biological indicator must be placed in the chamber before restarting the new cycle.

WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.

If a cycle cancels and the items in the load appear wet, hydrogen peroxide may be present. Wear chemical resistant latex, PVC (vinyl), or nitrile gloves while removing the items from the chamber, and while wiping off the items with a damp cloth. Discard contaminated cloth according to your health care facility's procedures.

Cycle Completed

When the cycle is complete, the Cycle Completed screen is displayed. The background of the screen is green to indicate a successfully completed cycle. The loudspeaker emits one long beep to indicate successful cycle completion.



Cycle Completed

03/09/07
15:40:23

Cycle Completed Successfully

Cycle Data:

Cycle Number: 22
Cycle Name: STANDARD
Start Time: 03/09/07 14:49:23
Completion Time: 03/09/07 15:38:45
Elapsed Time: 00:49:22
Operator: 92618

Figure 16. Successful STANDARD Cycle Completed.

1. Touch the **View Details** button to display the cycle history file for the just-completed cycle.
2. Touch the **Done** button to proceed.

Processing a Sterilized Load

When you touch the **Done** button, how the sterilizer responds depends upon the configuration of your sterilizer.

- If login is required before the door can be opened, the Login screen is displayed. When this occurs, enter your operator identification and password and touch **Enter.** The door opens and the load can be removed. The operator's name appears on the printout acknowledging the completion of the cycle.
- If no login is required for load removal, the door opens and the load can be removed.

WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.

If white residue is visible on the load, this is residue from the hydrogen peroxide stabilizer. Wear chemical resistant latex, PVC (vinyl), or nitrile gloves when removing a load with visible white residue. White residue can be minimized by making sure regular Planned Maintenance procedures are performed on your system. The system will inform you when planned maintenance is due. Please schedule your PM service in a timely manner.

- Refer to the cycle completion flowcharts for additional information.

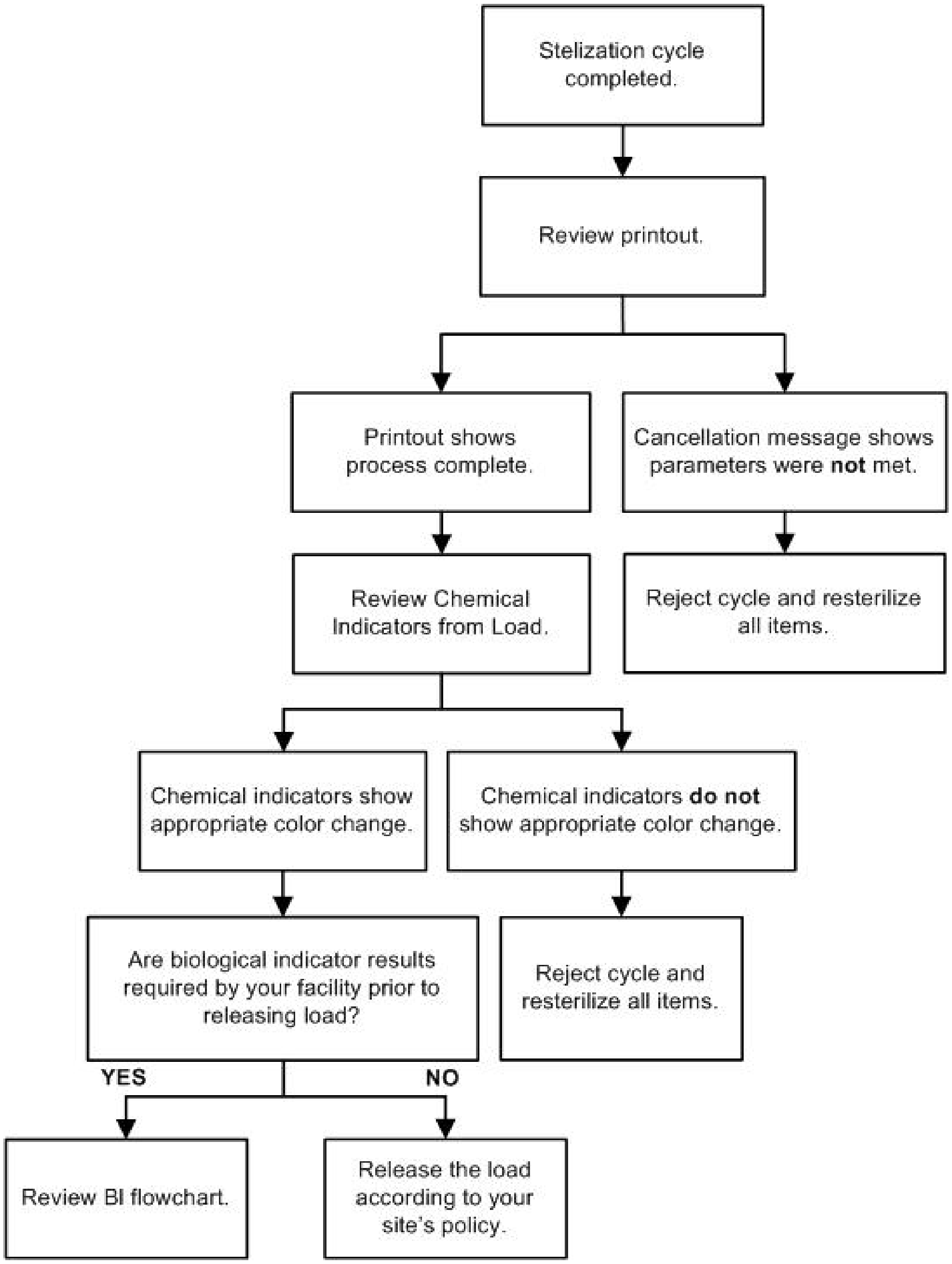
Inspecting Chemical Indicators

After ensuring that the chemical indicators exhibit the correct color change, and the cycle printout shows that all the necessary cycle parameters were met, the sterilized load is ready for immediate use, following your health care facility's policy. If the chemical indicators do not exhibit the correct color change, investigate the cause, repackage, and then reprocess the load.

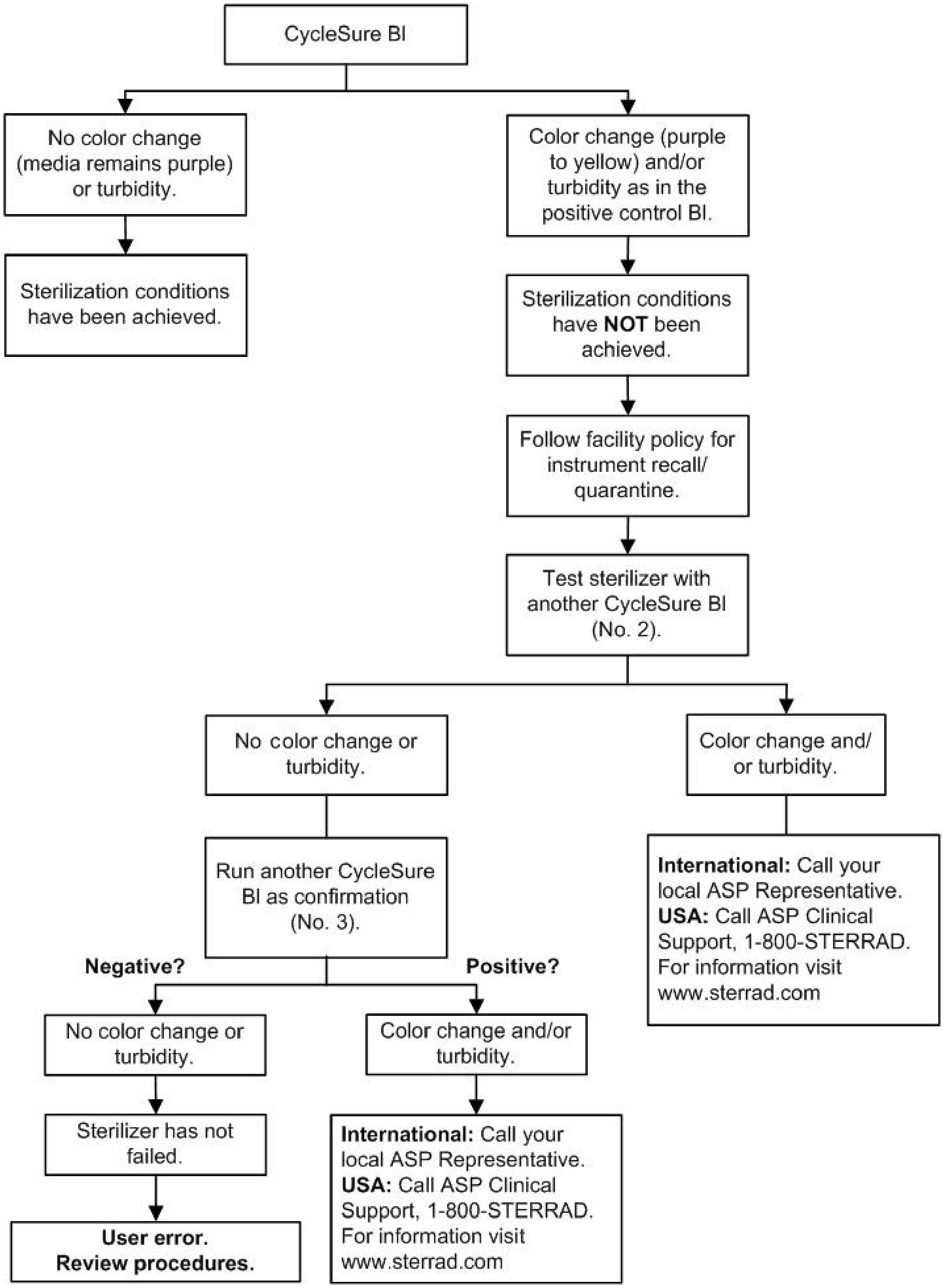
Processing Biological Indicators

Remove the biological indicator from the load and process it per its *Instructions for Use*. Refer to the flowcharts on the following pages for additional information.

Cycle Completion Flowchart


Stelization cycle completed.
Review printout.
Printout shows process complete.
Cancellation message shows parameters were **not** met.
Review Chemical Indicators from Load.
Reject cycle and resterilize all items.
Chemical indicators show appropriate color change.
Chemical indicators **do not** show appropriate color change.
Are biological indicator results required by your facility prior to releasing load?
Reject cycle and resterilize all items.
YES
NO
Review BI flowchart.
Release the load according to your site's policy.

STERRAD CYCLESURE® 24 Biological Indicator Flowchart


CycleSure BI
No color change (media remains purple) or turbidity.
Sterilization conditions have been achieved.
Color change (purple to yellow) and/or turbidity as in the positive control BI.
Sterilization conditions have **NOT** been achieved.
Follow facility policy for instrument recall/ quarantine.
Test sterilizer with another CycleSure BI (No. 2).
No color change or turbidity.
Run another CycleSure BI as confirmation (No. 3).
Color change and/ or turbidity.
International: Call your local ASP Representative. **USA:** Call ASP Clinical Support, 1-800-STERRAD. For information visit www.sterrad.com
Negative?
Positive?
No color change or turbidity.
Sterilizer has not failed.
User error. Review procedures.
Color change and/or turbidity.
International: Call your local ASP Representative. **USA:** Call ASP Clinical Support, 1-800-STERRAD. For information visit www.sterrad.com

Chapter 5.

Troubleshooting

✓ ***Note:*** *Repairs and adjustments should only be made by ASP trained and authorized personnel.*

Most sterilizer operating problems are accompanied by a system message. These messages are useful in determining the source of the problem. In many cases you can take remedial actions to return the sterilizer to normal operation. Because load related issues are the most frequent cause of cycle cancellation, the easiest solution is to repackage the load and restart the sterilizer when a cycle cancels. Be sure to replace biological and chemical indicators with new ones. In other cases, the problem may be caused by a component failure that requires adjustment or repair by an ASP Service Representative. Call your local ASP Representative for service information.

In the following table are messages that are displayed by the system. The messages are listed in alphabetical order. Some messages do not require action on your part and are merely statements of the system status. Other messages require that you insert a cassette, remove the cassette disposal box, or other such action. The display directs you what steps to take. If the cycle had cancelled, **wear chemical resistant latex, PVC (vinyl) or nitrile gloves** when removing the load.

Running Diagnostics

If the sterilizer or the information in the following table directs you to run diagnostics, remove the load and touch **Other Tests** from the Diagnostics menu. If you have received a message containing the word "temperature," touch **Temperature Tests**. (See the section on "Access Levels and Supervisor Tasks" for information on how to navigate to the Diagnostics menu.) If you run Diagnostics and the tests show that there are errors, contact your ASP Representative and report the diagnostic results. If the diagnostic tests pass with no errors, you can run cycles with your normal load.

System Message Table

Temperature Messages

WARNING! HOT SURFACES.

When a temperature message is displayed, this may mean that the interior of the sterilizer may be very hot. Do not touch the inside of the chamber, electrode, or doors with your bare or gloved hands. Allow the sterilizer to cool before touching interior surfaces.

A number of displayed messages concern the temperature of the system; e.g., doors, vaporizer, electrode, etc. These messages contain the word “temperature” and require that you run the temperature test in diagnostics. If the temperature test fails, or if the message is repeated, call your ASP Representative for further action.

Messages Not In This Table

If a displayed message is not found in the following table or in Appendix C5 (for network related messages), there is no remedy available that you may safely perform. Call your ASP Representative for further action.

If this message appears. . .	Do this . . .
Cannot Dispose Cassette, Run Diagnostics	The cassette did not drop into the disposal box. Remove the load and run diagnostics.
Cassette Accepted, Positioning	No action required.
Cassette Detected, Verifying	No action required.
Cassette Did Not Index	A cassette was unable to advance to the next cell. Remove the load and run diagnostics.
Cassette Expired, Disposing Cassette	Insert a new cassette.
Cassette Expiry Found During Start Cycle	The cassette was found to be expired when the Start Cycle button was pressed. Dispose of the cassette and insert new cassette.
Cassette Out Of Date, Disposing Cassette	The cassette has been in the sterilizer for 10 days or the cassette has expired. Insert new cassette.
Cassette System Timeout When Piercing	The delivery subsystem is not responding. Remove the load and run diagnostics.

If this message appears. . .	Do this . . .
Cassette Used, Disposing	The inserted cassette does not have any unused cells remaining. Insert a new cassette.
Cycle Canceled By Operator	The operator canceled the cycle. Repackage the load. Restart the cycle after cancellation is complete.
Delivery System Not Ready	Delivery system not responding. Remove the load and run diagnostics.
Disposing Cassette	No action required.
Door Sensor Fault	Door malfunction. Reboot the system. If the message persists, call your ASP Representative.
Function Available on Other Side	Control of the sterilizer is on the other side of the unit.
H_2O_2 Adjustment Failed. Please Call ASP.	Call your ASP Customer Support Representative.
H_2O_2 ADJUSTMENT FAILED OPEN DOOR, CLEAR UV PATHWAY, CLEAN UV LENS AND CLOSE DOOR. PRESS OK BUTTON WHEN READY TO RESTART THE STERILIZER.	Follow the instruction displayed. Press the OK button on the display message.
H_2O_2 Adjustment In Progress	The intensity of the UV lamp is being adjusted. Wait 5 minutes for adjustment to be completed.
H_2O_2 Bulb Warming Up, Please Wait…	No action needed.
H_2O_2 Bulb/Detector Fault	H_2O_2 detector malfunction. Run diagnostics.
H_2O_2 Curve Area Too Low. Verify That The Load Is Not Blocking The UV Light Path	Load is absorbing too much peroxide. Remove absorbing materials from the load, repackage, and restart the cycle. If the problem persists, call your ASP Representative.
H_2O_2 Monitor Failure	H_2O_2 bulb or detector malfunction. Remove the load and run diagnostics.
WARNING! HYDROGEN PEROXIDE MAY BE PRESENT. ***Wear chemical resist ant latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.***	
H_2O_2 Peak Too Low	The load is absorbing too much peroxide. Remove the absorbent materials from the load, repackage, and restart the cycle. If the problem persists, call your ASP Representative.

<table>
<tr><th>If this message appears. . .</th><th>Do this . . .</th></tr>
<tr><td>H_2O_2 Peak Constant Too High</td><td>The load is decomposing the H_2O_2. Check the load for absorbent materials. Repackage, and restart the cycle. If the problem persists, call your ASP Representative.</td></tr>
<tr><td colspan="2">WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.
<i>Wear chemical resistant latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.</i></td></tr>
<tr><td>H_2O_2 Rate Outside the Calibrated Range</td><td>Reboot the system. If the problem persists, call your ASP Representative.</td></tr>
<tr><td>H_2O_2 Sensor Fault</td><td>Reboot the system. If the problem persists, call your ASP Representative.</td></tr>
<tr><td>High Plasma Power</td><td>The plasma power is out of specification. Remove the load and run diagnostics.</td></tr>
<tr><td>Invalid Key Code. Please Enter A Valid Code</td><td>Press the OK button and reenter a valid key code.</td></tr>
<tr><td>Invalid Load Items File</td><td>Press the Back button and reinsert the USB memory stick.</td></tr>
<tr><td colspan="2">WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.
<i>Wear chemical resistant latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.</i></td></tr>
<tr><td>Load May Contain H_2O_2</td><td>Residual peroxide may be present on the load or chamber walls due to a cancelled cycle or system malfunction. Wearing chemical resistant latex, PVC (vinyl), or nitrile gloves, repackage the load and restart the cycle. If the problem persists, call your ASP Representative.</td></tr>
<tr><td colspan="2">WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.
<i>Wear chemical resistant latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.</i></td></tr>
<tr><td>Low Plasma Power</td><td>The plasma power is out of specification. Remove the load and run diagnostics.</td></tr>
<tr><td>No File Found</td><td>Press OK. Reinsert the USB memory stick.</td></tr>
<tr><td>Other Door Is Opened</td><td>Close the door on the other side of the sterilizer.</td></tr>
<tr><td>Please Close Door</td><td>Touch the close door display or the door foot pad to close the door.</td></tr>
</table>

<table>
<tr><th>If this message appears. . .</th><th>Do this . . .</th></tr>
<tr><td>Please Enter Valid User Name and Password</td><td>After the valid user name and password are entered, press OK.</td></tr>
<tr><td>Please Insert New Cassette</td><td>Insert a new, unused cassette.</td></tr>
<tr><td colspan="2">WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.
<i>Wear chemical resistant latex, PVC (vinyl), or nitrile gloves whenever handling new or used cassettes.</i></td></tr>
<tr><td>Please Remove Cassette And Verify Cassette Type</td><td>Wrong cassette type. Confirm that the cassette is a STERRAD® 100NX® cassette.</td></tr>
<tr><td>Please Wait While Graph Loads</td><td>No action required.</td></tr>
<tr><td colspan="2">WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.
<i>Wear chemical resistant latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.</i></td></tr>
<tr><td>Power Fail Cancellation</td><td>A power failure occurred during a cycle. Repackage the load and restart the cycle. If the problem persists, call your ASP Representative.</td></tr>
<tr><td colspan="2">WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.
<i>Wear chemical resistant latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.</i></td></tr>
<tr><td>Pressure Check Failed</td><td>Load is absorbing too much peroxide. Remove absorbing materials from the load, repackage, and restart the cycle.
If the problem persists, call your ASP Representative.</td></tr>
<tr><td>Pressure Out Of Range (High)</td><td>Vacuum system malfunction. Remove the load and run diagnostics.</td></tr>
<tr><td>Pressure Out Of Range (Low)</td><td>Vacuum system malfunction. Remove the load and run diagnostics.</td></tr>
<tr><td>Printer Is Out Of Paper. Please Load A New Roll.</td><td>Load paper into the printer.</td></tr>
<tr><td>Printing Is In Progress</td><td>No action required.</td></tr>
<tr><td>RFID Data Error, Ejecting Cassette, Verify Cassette Orientation</td><td>Cassette will automatically eject. Insert a valid cassette</td></tr>
<tr><td>Stage Timeout</td><td>Remove the load and run diagnostics.</td></tr>
<tr><td colspan="2">WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.
<i>Wear chemical resistant latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.</i></td></tr>
</table>

If this message appears. . .	**Do this . . .**
Unable to Evacuate Chamber . . . Ensure Load is Dry before Starting Cycle	Remove the load and run diagnostics. Reboot the system. If the problem persists, call your ASP Representative.
Unable to Open One Second Data File	Replace the PCMCIA card with a new one.
UV Path Is Blocked, Open Door And Clear Pathway	Object is blocking the UV path. Verify that the shelves and/or the load are not blocking the path. If the problem persists, call your ASP Representative.
Warming Up, Please Wait…	No action needed.
	WARNING! HYDROGEN PEROXIDE MAY BE PRESENT. ***Wear chemical resistant latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.***
Would You Like to Troubleshoot?	Remove the load and run diagnostics. If the problem persists, call your ASP Representative.

Call Your ASP Representative

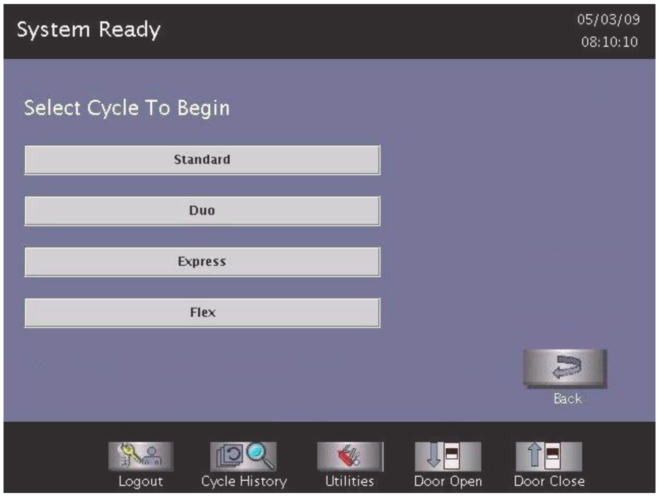
If you encounter a problem or a system message that is not covered in the this user's guide, do not attempt to perform repairs or adjustments to the STERRAD® 100NX® Sterilizer. Call your local ASP Representative for more information.

Chapter 6.

Sterilizer Overview

Sterilizer Cycles

The following display shows all the cycles available for the STERRAD® 100NX® Sterilizer. This guide contains detailed instructions for each cycle. Make sure you understand the differences in the cycles and what types of instruments can be sterilized in each cycle.



System Ready

05/03/09
08:10:10

Select Cycle To Begin

Standard
Duo
Express
Flex
Back
Logout
Cycle History
Utilities
Door Open
Door Close

Figure 17. Select Cycle Display Showing All Cycles. Your display may be different depending on the cycles installed and enabled for use. Supervisor Access is required to enable installed cycles.

Sterilizer Features

The cassette slot, the cassette drawer, the touch screen, PCMCIA slot (inside the access panel), the chamber door, the printer, and the foot pad are found on the input side of the sterilizer (the front of single-door units). On a two door unit the touch screen, chamber door, foot pad, and printer are found on both the input and output sides. The main power switch is located on the left (your left) front side of the sterilizer. The I/O interface is located on the right (your right) front side of the sterilizer. See the sections on Data Transfer and Rebooting the System for locations of the power switch and USB port.

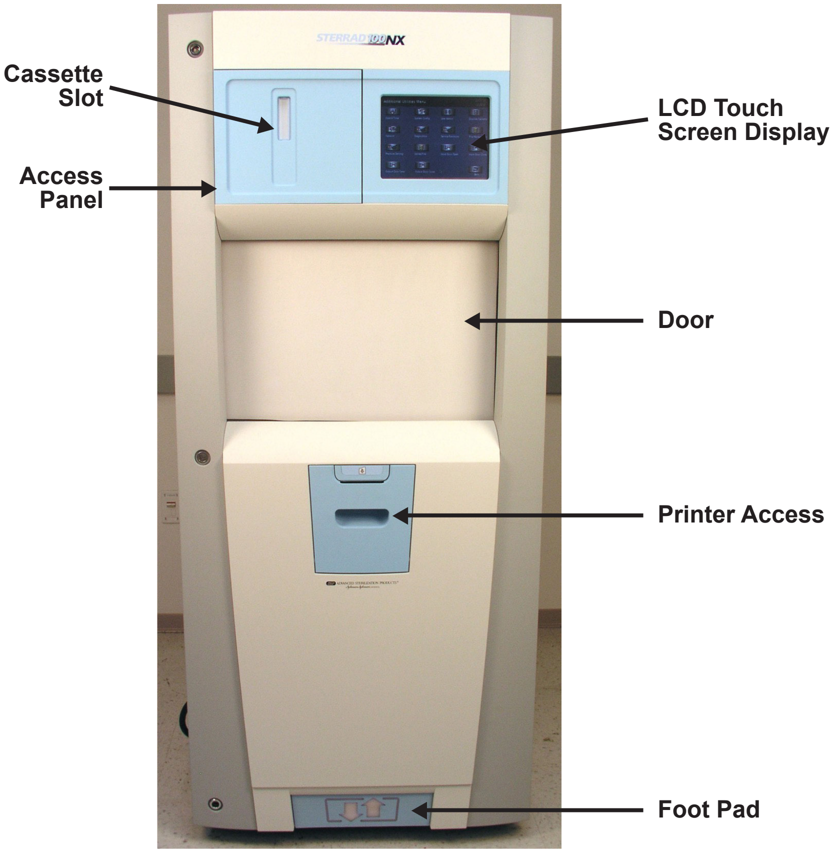


**Figure18. The STERRAD® 100NX® Sterilizer.
Not shown: The power switch is at the lower left and the USB port is at the lower right.**

- The sterilizer is operated by using the touch screen to begin a cycle, enter load information, monitor the cycle and perform diagnostics.
- A cassette is inserted into the sterilizer through the cassette slot.

- The items to be sterilized are placed on the shelves and the door is closed using either the close door button on the touch screen or by tapping the foot pad with your foot. The foot pad is located on the lower portion of the front panel.

Load information and cycle notes are entered if desired, a cycle is selected and the chosen cycle is then started. At the conclusion of the cycle the items are removed and are ready for storage or immediate use.

If the system is equipped with 2 doors, the load is inserted from the input side and removed from the output side. On 2 door units, the touch screen and door can be used only from the active side; both doors cannot be opened at the same time.

Cassette

The cassette contains sealed capsules of hydrogen peroxide solution. Each cassette has coded information that provides displayed details on the cassette expiration date, manufacturer, and cell status including cycle completion information. The sterilizer pulls the cassette through the slot and moves it into the machine, keeping it there until the cassette has been used.

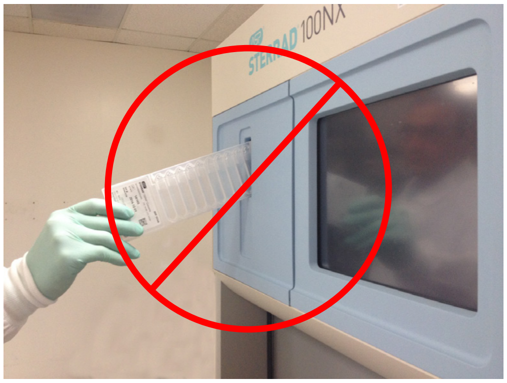


Figure 19a. Do not insert the cassette at an angle.

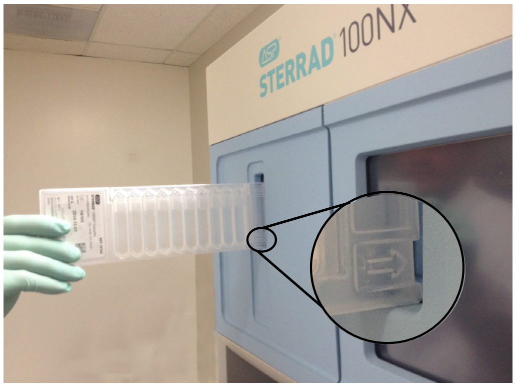


Figure 19b. Position the cassette so that the arrows are pointing straight into the cassette door slot of the sterilizer.

WARNING! HYDROGEN PEROXIDE IS CORROSIVE.
Concentrated hydrogen peroxide is corrosive to skin, eyes, nose, throat, lungs, and the gastrointestinal tract. Always wear chemical resistant latex, PVC (vinyl), or nitrile gloves when handling new or used cassettes and while removing items from the sterilizer following a cancelled cycle. Following a cancelled cycle, if items in the load show any visible moisture or liquid, hydrogen peroxide may be present.

Cassette Disposal Box

After processing of the cassette, the sterilizer automatically discards it into the cassette disposal box. The cassette disposal box holds **2** used cassettes. When the box has the maximum number of cassettes, the sterilizer displays a message indicating that the box must be replaced. The cassette disposal box must be closed to permit safe disposal of cassettes. Refer to the “Maintenance” chapter for additional information.

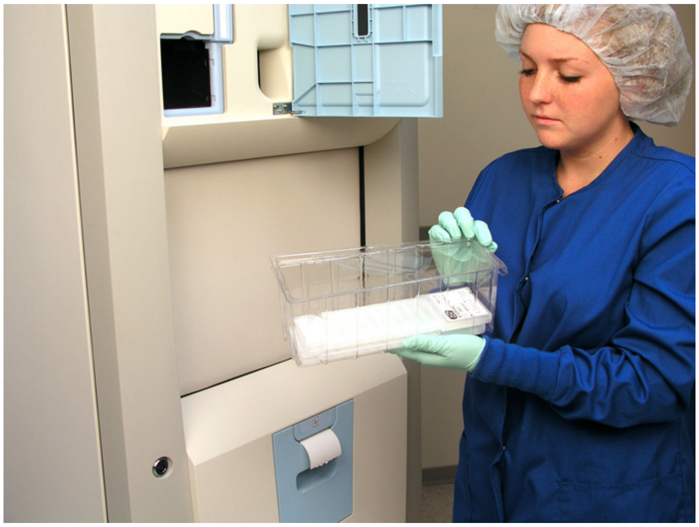


Figure 20. Cassette Disposal Box.

Touch Screen and Speaker

The sterilizer displays information and allows you to enter commands on the color touch screen display. By touching buttons displayed on the screen, you can enter letters and numbers, make selections, and start and stop the sterilizer.

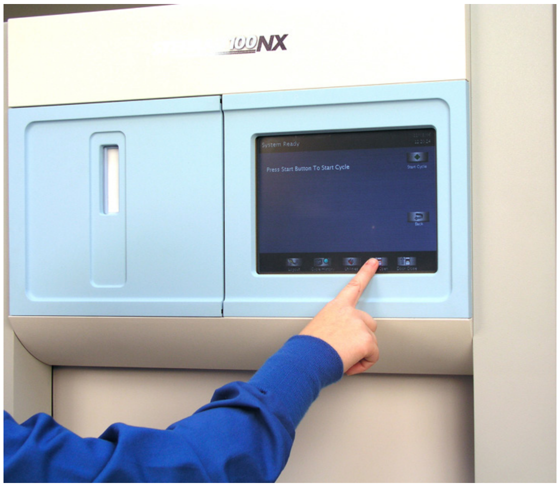


Figure 21. Using the Touch Screen.

An internal loudspeaker emits "beep" tones to call for user attention or indicate errors. A single long beep indicates a successfully completed cycle. A series of ten short beeps indicates a canceled cycle.

Chamber

The load is placed in the chamber for sterilization. The chamber walls and doors contain heaters that keep the chamber interior warm during operation. When the chamber door(s) are closed, a vacuum-tight seal is created, allowing the chamber atmosphere to be evacuated during operation.

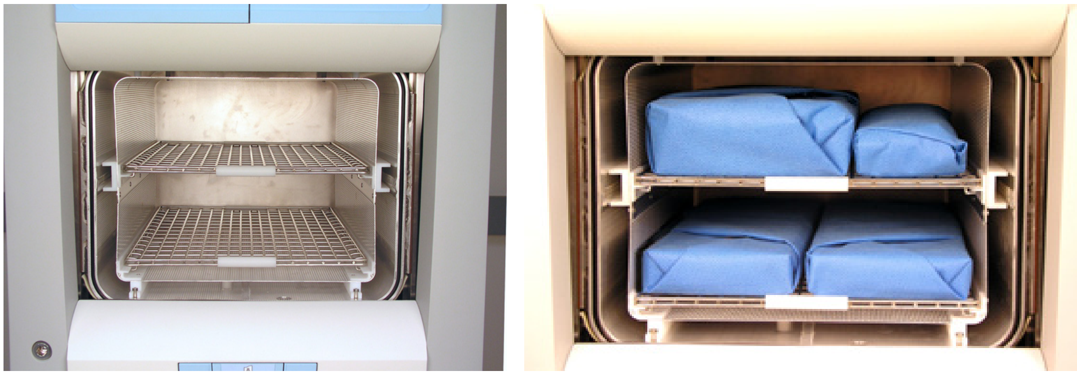


Figure 22. The STERRAD® 100NX® Chamber Empty and With a Typical Standard Cycle Load Correctly Placed.

The chamber contains 2 slide-out shelves to permit efficient loading. Inside the chamber, surrounding the shelves is a metal screen (the electrode) that helps generate plasma during operation.

Printer

The sterilizer has an integrated internal printer located in the front panel. On two door units, a printer is located in the main panel on each side. The printer prints cycle reports and other information on a roll of thermal paper. The printer features easy, drop-in paper loading and requires no ink cartridges. (The system is also designed to interface to a second, external printer that is USB-compliant and supports PCL-3 protocol.)

- The handle is squeezed and the door is pulled toward you to open the printer door for printer paper replacement.
- The top button advances the paper.

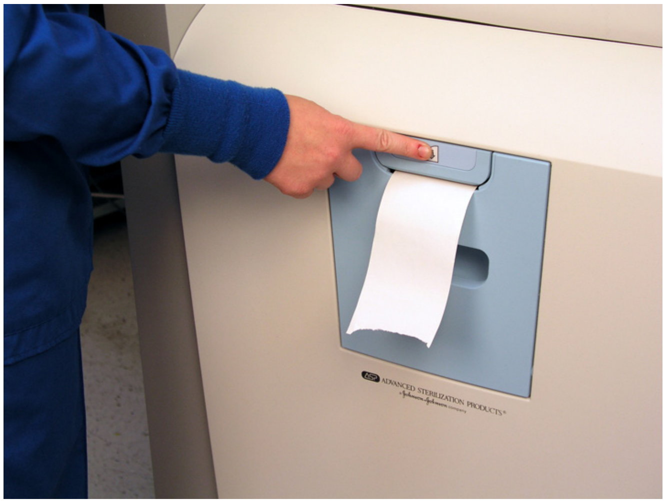


Figure 23. STERRAD® 100NX® Printer Paper Advance Button.

Touch Screen Data Entry

The following figure shows a typical data entry screen. The typewriter "keys" input the indicated character each time a key is touched. Touch the screen to move the cursor from place-to-place. The load list can be predefined and used repeatedly.

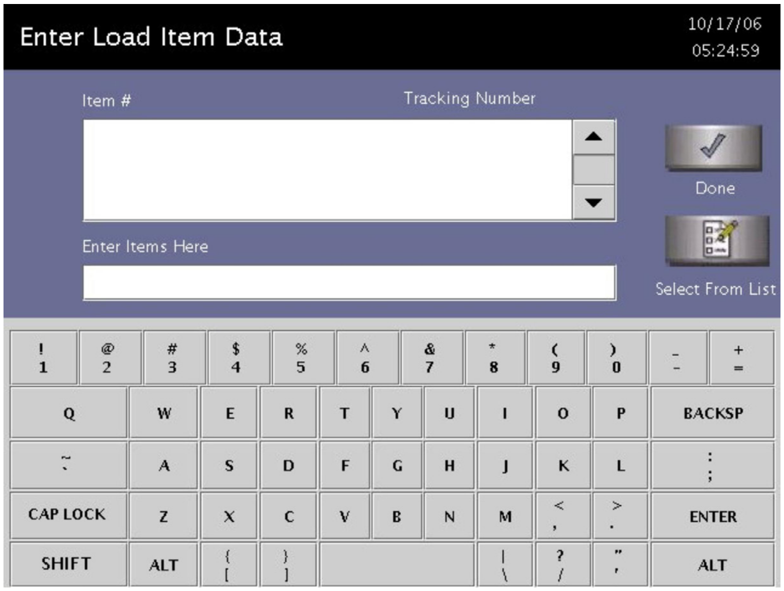

Enter Load Item Data
10/17/06
05:24:59
Item #
Tracking Number
Done
Enter Items Here
Select From List
! 1
@ 2
# 3
$ 4
% 5
^ 6
& 7
* 8
(9
) 0
_ -
+ =
Q W E R T Y U I O P
BACKSP
~ `
A S D F G H J K L
: ;
CAP LOCK
Z X C V B N M
< ,
> .
ENTER
SHIFT
ALT
{ [
}]
| \
? /
" '
ALT

Figure 24. Example of a Data Entry Screen.

Function Buttons

Most screens provide function buttons that display other screens or select sterilizer functions. Common function buttons are shown in the following table.

Button	Function
✓	**Done.** Touch this button to indicate that you are finished using the screen.
↩	**Back.** Touch this button to return to a prior screen.
🔍	**View.** Touch this button to view the selected report or file.
🖨	**Print.** Touch this button to print the selected report or file.
▽	**Cancel.** Touch this button to cancel the entry you just made.

Chapter 7.

Maintenance

✓ ***Note:*** *Repairs and adjustments should only be attempted by experienced technicians who are fully trained to maintain and repair the STERRAD® 100NX® Sterilizer. Use of unauthorized parts for maintenance or repair could cause personal injury, result in costly damage, or sterilizer malfunction and voids the warranty.*

Automatic Maintenance

The adjustment of the hydrogen peroxide monitoring lamp is performed automatically by the sterilizer software. The user does not have to perform any task to start this procedure.

Automatic Lamp Adjustment

When the sterilizer shows the System Ready screen, the message "Auto Adjustment in Progress" will be displayed while the sterilizer adjusts the intensity of the UV lamp. This function can take approximately 5 minutes to complete. The automatic adjustment will take place if the lamp voltage is below a preset limit.

Manual Maintenance

The following maintenance procedures are performed by the user:

- Disposing of cassettes.
- Inserting a new cassette disposal box.
- Replacing the printer paper roll.
- Cleaning the sterilizer exterior.
- Cleaning the hydrogen peroxide monitor detector lens.
- Replacing the air filter.
- Replacing the PCMCIA card (if desired).
- Disposing of a sterilizer.

These tasks are performed when needed. The printer paper is replaced when the roll is empty. The sterilizer exterior should be cleaned only when necessary. This chapter provides step-by-step instructions on how to perform these maintenance tasks. Information on inserting a cassette box follows the disposal section.

Disposing of Cassettes

When a cassette is empty the sterilizer automatically moves it to the cassette disposal box. The screen displays a message instructing you which actions to take next. When the cassette disposal box contains 2 cassettes, it is full, and you must dispose of the full cassette disposal box. For safety reasons, you **must** use the cassette disposal box to dispose of cassettes. Never reuse a cassette disposal box. Once a cassette disposal box has been removed, a new cassette disposal box must be inserted.

Removing a Cassette Disposal Box

WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.
Wear chemical resistant latex, PVC (vinyl), or nitrile gloves. This will protect you from contact with any residual hydrogen peroxide that may be present in the cassettes.

1. Open the cassette access door. Pull the tab on the cassette disposal box to more easily slide it completely out.

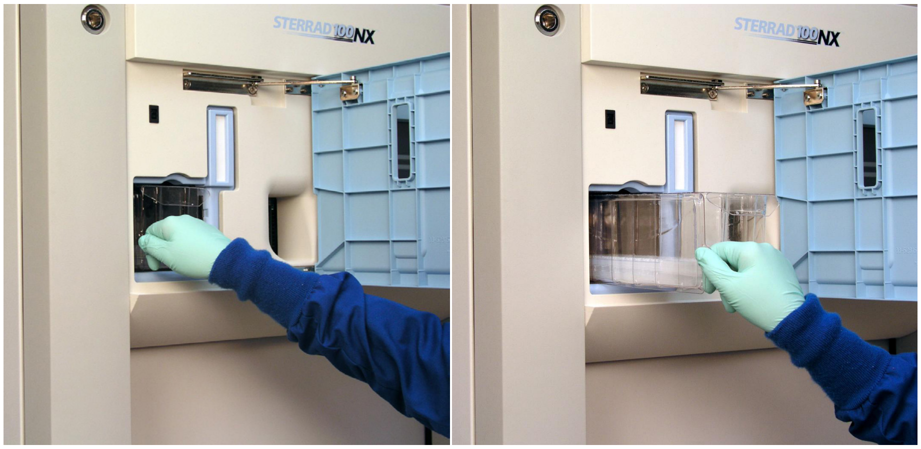


Figure 25. Open the Access Panel and Remove the Used Cassette Box.

2. Close the lid by pinching it shut along the edge.

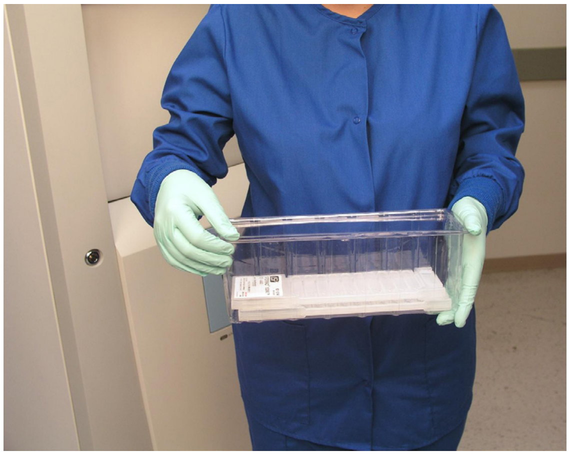


Figure 26. Pinch the Edge of the Lid to Close the Box.

3. Dispose of the closed cassette box according to your health care facility's policy.

4. Insert a new box making sure the lid is open and not caught in the opening, and the tab is facing you.

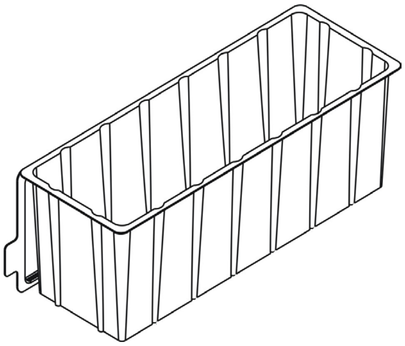


Figure 27. Insert the New Cassette Box with the Lid Open so the Tab is on the Left.

5. Close the access panel.

Replacing the Printer Paper

When the printer paper roll is empty, the sterilizer displays a message “Printer is out of paper. Please load a new roll.”

1. Open the printer by pushing or squeezing up on the handle as shown. The printer door opens toward you.

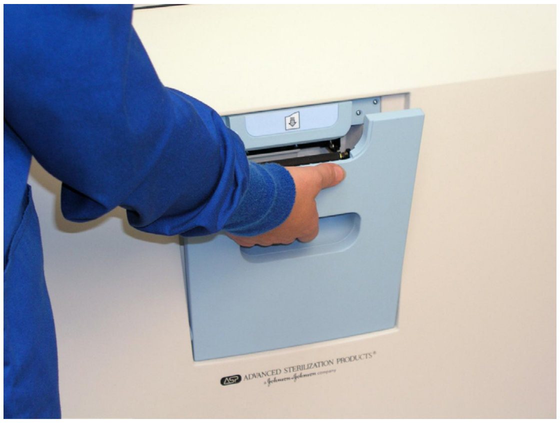


Figure 28. Open the Printer.

2. The empty paper roll rests on the bottom of the printer door. Remove the empty roll.

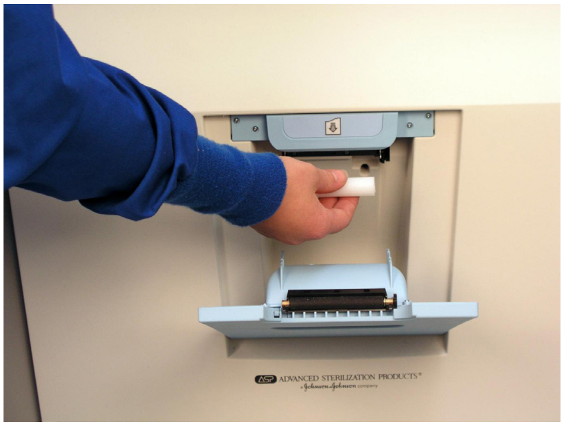


Figure 29. Remove the Empty Paper Roll.

3. Insert a new paper roll as shown in the following figure. The paper should feed from the top of the roll.

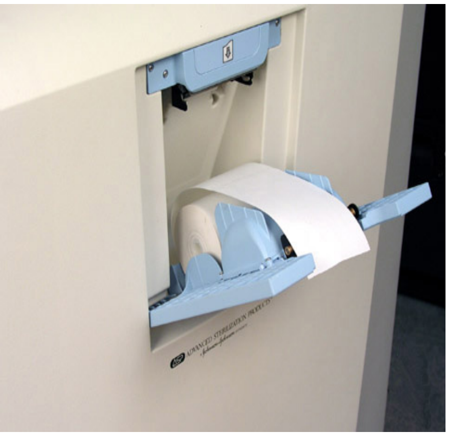


Figure 30. Insert a New Paper Roll.

4. Pull a short length of paper over the top of the printer door.
5. Align the paper so that it fits between the two paper guides on the top of the printer door.

6. Push the door shut making sure the paper stays in place.

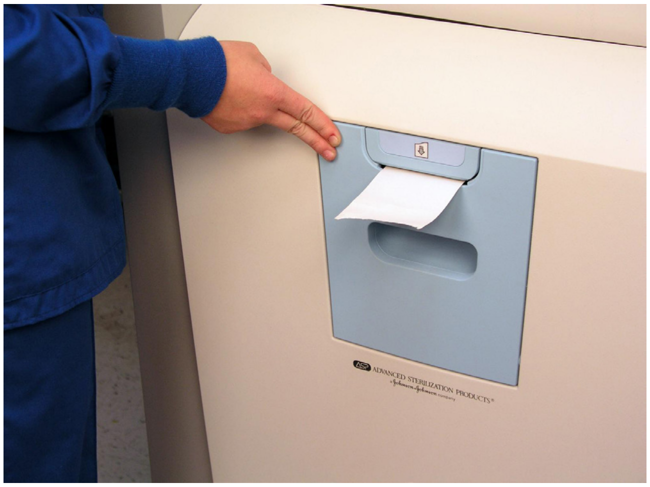

ADVANCED STERILIZATION PRODUCTS
a Johnson & Johnson company

Figure 31. Make sure the Printer Door Latches Securely and the Paper is in Place.

7. Press the paper advance button. Check the alignment of the paper and make certain it does not jam or misfeed.

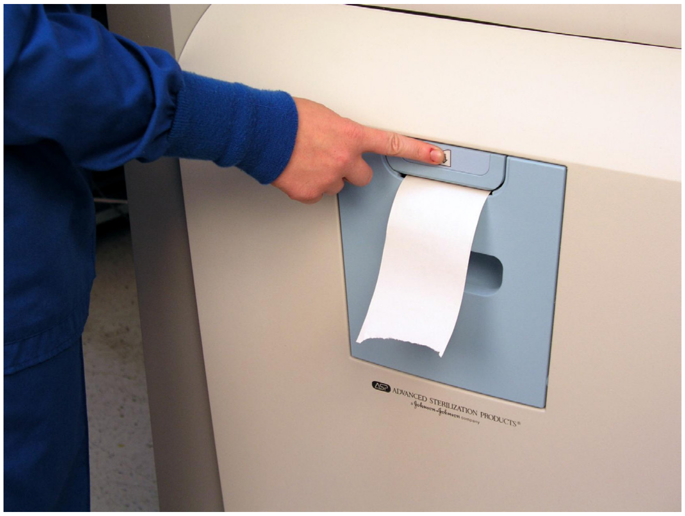

ADVANCED STERILIZATION PRODUCTS
a Johnson & Johnson company

Figure 32. Press the Paper Advance Button.

8. When the paper has advanced normally, tear off the used strip in an upward direction. Paper replacement is now complete.

Cleaning the Sterilizer Exterior

✓ **Note:** *Do not attempt to clean the chamber, door, interior surfaces, shelves, or electrode. If these items need cleaning, call your local ASP Representative for assistance.*

The sterilizer exterior can be cleaned with a soft cloth and a mild, nonabrasive detergent solution if necessary. When cleaning the sterilizer exterior, follow these guidelines:

1. Turn off the power to the sterilizer before cleaning the exterior.
2. Never allow cleaning solution or water to enter the interior or chamber. Moisten a cloth with nonabrasive detergent solution and use the damp cloth to clean the surfaces.
3. Do not spray cleaning solution directly on the touch screen. Use a dampened cloth to clean the screen.
4. If you have any questions about proper cleaning techniques, in the U.S.A. please call your local ASP Representative before proceeding. Failure to follow these guidelines may result in damage to the sterilizer and may void the warranty.

Cleaning the Hydrogen Peroxide Monitor Detector Lens

The hydrogen peroxide monitor lens is located on the input side of the sterilizer. The lens must be kept clean. Wipe off the lens once every three months or when an accumulation of debris is noted. This is shown in the following figure.

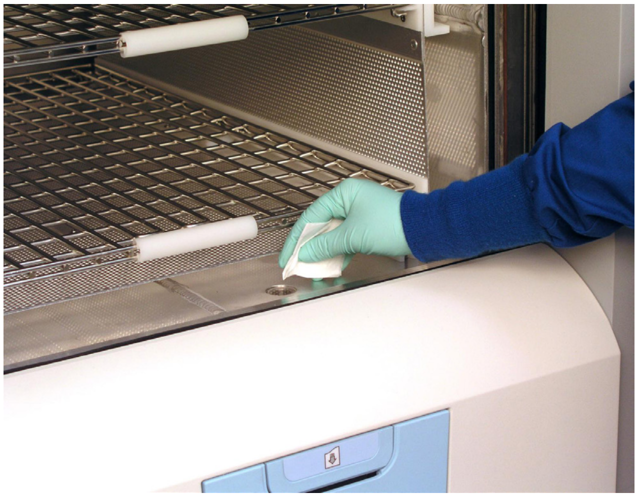


Figure 33. Cleaning the Hydrogen Peroxide Monitor Lens.

1. Always use a lint-free cloth to clean the lens.
2. Moisten the cloth with isopropyl alcohol. Never use an abrasive cleanser.
3. Wipe the lens to remove any accumulated debris.

PCMCIA Card Handling and Replacement

The PCMCIA card contains the flash memory used to store cycle data. It should not be removed arbitrarily. If you need to remove or replace it, use the following steps:

1. Turn off the sterilizer, or go to the “Additional Utilities” menu and press the PCMCIA button. Either method allows you to safely remove the PCMCIA card.
2. Open the cassette access door.
3. Eject the PCMCIA card by pressing the eject button on the top of the card slot (see the following figure).

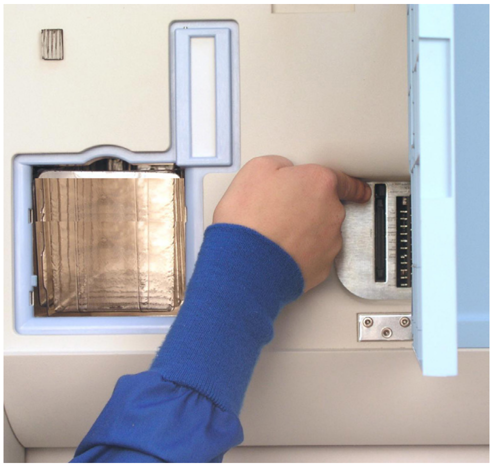


Figure 34. Press the Button at the Top of the Card Slot to Eject the PCMCIA Card.

To reinsert the PCMCIA card, do the following:

1. Examine the PCMCIA card and note the location of the label.
2. Orient the PCMCIA card so that the side of the card with the label faces left.

3. Insert the card into the PCMCIA card slot.
4. Press the end of the PCMCIA card until the card is firmly seated in the slot (you will feel a “click” as the card is seated in the connector).

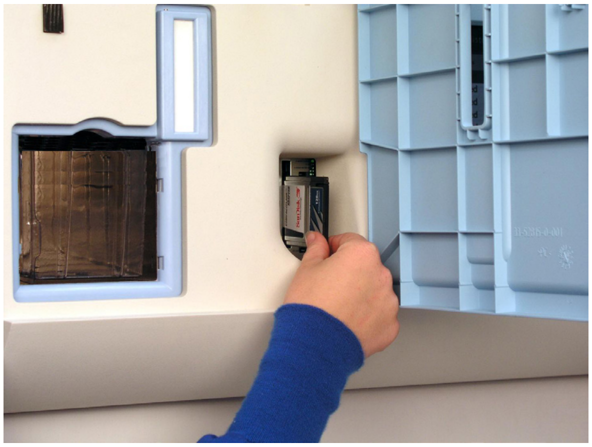


Figure 35. Insert the PCMCIA Card Correctly.

✓ ***Note:*** *The STERRAD® 100NX® Sterilizer will not operate unless the PCMCIA card is properly installed.*

Data Transfer Using a Memory Stick

A memory stick can be inserted in to the USB port located on the right (your right) side of the sterilizer. Go to the Cycle History screen and select **Data Transfer**, then **USB Save**. Select cycle data to be transferred and data type.

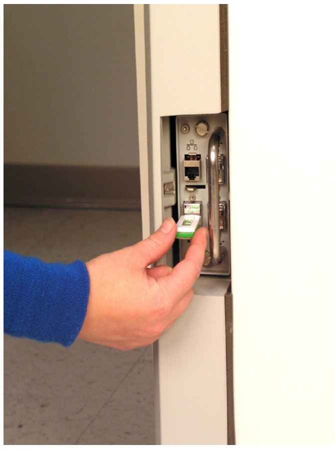


Figure 36. Insert the Memory Stick into The USB Port.

Rebooting the System

If it becomes necessary to reboot the system, flip the main switch on the sterilizer to turn off the system and then turn it back on.

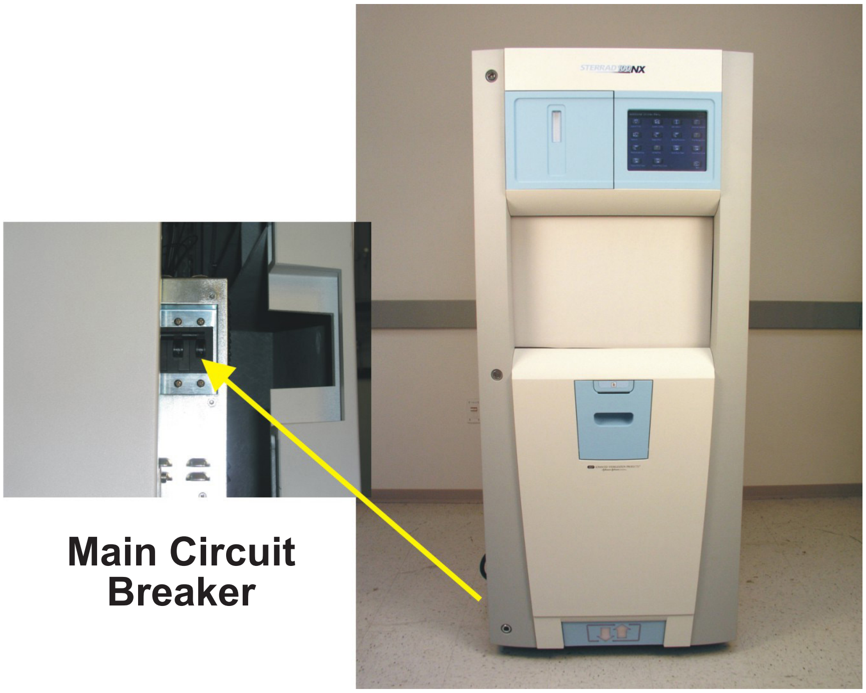


Figure 37. The Main Power Switch/Circuit Breaker is Located on the Side of the Sterilizer at your Left.

Sterilizer Disposal

Applicable in the EU: All electrical and electronic equipment (including batteries) must be returned to a waste collection system or treatment and recycling facility. Follow decontamination instructions before returning waste. Contact your ASP Representative if you need assistance.

Other Countries: Prior to disposal of the sterilizer, user must follow decontamination instructions. The disposal of infectious waste, electronic circuit boards and other electronic components (including batteries) are regulated in many countries; (e.g., by the US Environmental Protection

Agency). Please ensure compliance with all International, Federal, State, and Local regulations before disposal. Contact your ASP Representative for additional information.

Chapter 8.

Reports and Files

Displayed Reports

Users with Operator-level access can display the Cycle History files. Users with Supervisor-level access can display the Cycle History files, as well as Calibration files and Diagnostic files.

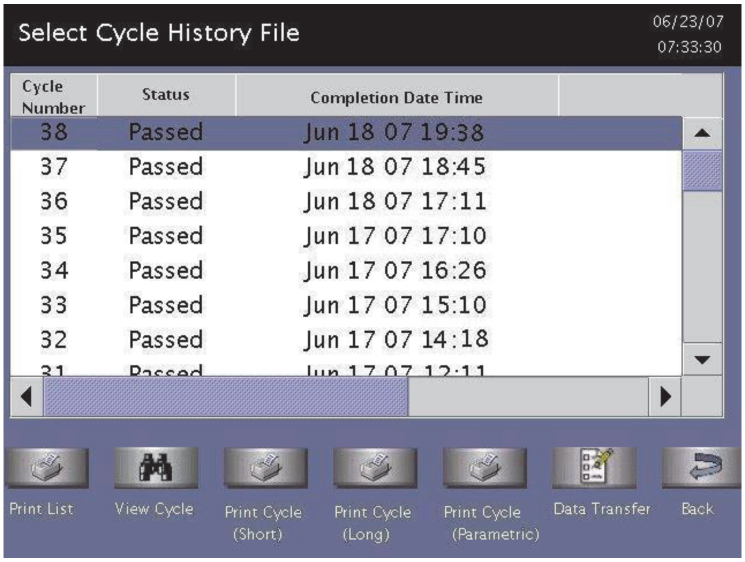
All files that are displayed can be printed by touching the **Print** button on the file display screen.

Cycle History

Cycle history data is stored in the sterilizer's memory. The memory holds data from the last 200 cycles. After 200 cycles are completed, the oldest cycle history record is overwritten with new data from the 201st cycle. If your sterilizer is configured with the optional network connection, cycle history data can be periodically uploaded to a host computer and preserved permanently if desired.

When you touch the **View Cycle History** button on any screen where the button appears, the program displays the Select Cycle History screen. The list box shows the cycle number, status, completion date and time, and reason for cancellation (if applicable) for all cycle history records currently in the sterilizer's memory.

Touch the scroll bars to scroll through the list. Touch the line you wish to select.



Select Cycle History File

06/23/07
07:33:30

Cycle Number	Status	Completion Date Time
38	Passed	Jun 18 07 19:38
37	Passed	Jun 18 07 18:45
36	Passed	Jun 18 07 17:11
35	Passed	Jun 17 07 17:10
34	Passed	Jun 17 07 16:26
33	Passed	Jun 17 07 15:10
32	Passed	Jun 17 07 14:18

Figure 38. Select Cycle History File.

Print List prints a list of all cycle history files stored in the sterilizer.

View Cycle displays the selected Cycle History file on the screen.

Print Cycle (Short) prints a short-format report of the selected cycle history file.

Print Cycle (Long) prints a long-format report of the selected cycle history file.

Parametric Print prints a parameter format report of the selected cycle history file (external printer required).

Data Transfer – allows you to transfer the cycle information to a USB memory stick or to a networked PC.

Back returns you to the previous screen.

Printed Reports

Every time a cycle is completed, a cycle completion report is printed. Depending upon how your sterilizer has been configured, the report will either be a short-format report, a parametric report, or a long-format report. Each report extracts data from the cycle history record created by the cycle. The short-format report indicates the cycle status (Passed or Failed), date, time, operator and load information. The parametric report contains much more detail than the short report, but is less extensive than the long-format report. The long-format report includes all of the data in the short report plus detailed information about each stage of the sterilization cycle.

Short Report

The short-format report lists identifying information about the cycle, shows the cycle status, lists the date and duration of the cycle, and shows operator and load identifying information. The short-format report is useful for record keeping purposes and providing traceability of sterilized loads.

Parametric Report

The parametric format report shows single-point values for a certain number of parameters. It is a more confined report than the long printout and contains a table of all critical parameters and their values. It is only available if an external printer is attached.

Long Report

The long-format report lists detailed information about the cycle, shows the cycle status, lists the date and duration of the cycle, shows operator and load identifying information, and provides detailed data about the operation of the sterilizer, including temperatures, pressures, plasma measurements, and sterilant concentrations throughout the cycle. The long-format report is useful for detailed cycle quality control and contains valuable diagnostics information for ASP Service Representatives.

Chapter 9.

Access Levels and Supervisor Tasks

Overview

Users with Supervisor-level access privileges (see below) are permitted to perform a set of restricted sterilizer functions. These functions are not used in daily sterilizer operation and some of them are designed to control access, manage system records, and perform advanced diagnostic functions.

Access Levels

The STERRAD® 100NX® Sterilizer can be configured to require that all users enter a valid operator identification and password before operating the sterilizer. This access control is enabled through the System Configuration screen and user identifications, passwords, and access levels are assigned and maintained through the User Administration screens.

There are three levels of access available. Each is associated with a different subset of permitted operations.

Operator-level access is designed to permit a user to perform tasks associated with the daily operation of the sterilizer. These privileges allow a user to:

- Select, start, and cancel a cycle.
- Enter load item information and cycle notes.
- Print a cycle history report and view cycle history files.
- Run diagnostics when a cycle cancels.

Supervisor-level access includes all of the privileges of Operator-level access and additionally provides the ability to:

- Add, delete, and modify user names, passwords, and access levels.
- Select, view, and print all sterilizer files.
- Run diagnostic tests and print reports.
- Set date and time.
- Configure sterilizer features.
- Configure the network connection and upload data to the network.

Service-level access is only for use by ASP Service Representatives.

Additional Utilities Menu

The Additional Utilities Menu is available only to users with Supervisor- or Service-level access privileges. If a user with Operator-level privileges touches an **Additional Utilities** button on any screen, the Login screen will be displayed with the message: “Supervisor- or Service-Level Login Required.”

The Additional Utilities Menu allows supervisors to configure the sterilizer and the network connection, set the date and time, set up and maintain user privileges, view and print files, perform diagnostic tests, and dispose of cassettes.

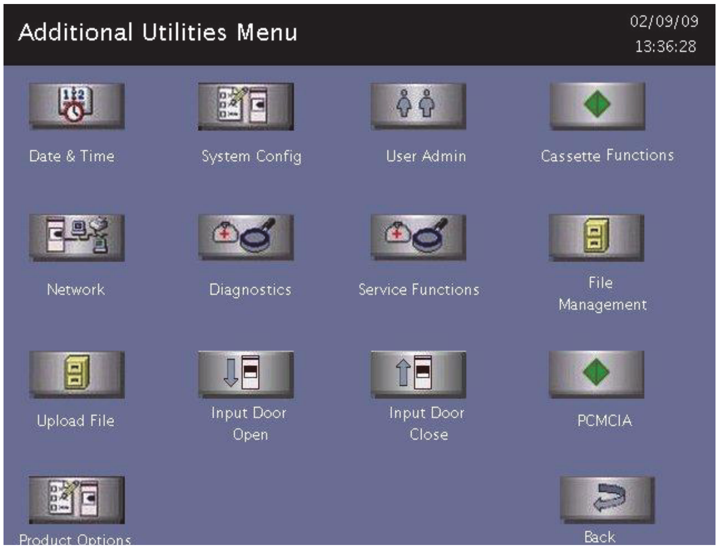

Additional Utilities Menu
02/09/09
13:36:28
Date & Time
System Config
User Admin
Cassette Functions
Network
Diagnostics
Service Functions
File Management
Upload File
Input Door Open
Input Door Close
PCMCIA
Product Options
Back

Figure 39. Additional Utilities Menu.

Date & Time allows you to set the date, time, time zone, and formats used for displaying and printing date and time.

System Config allows you to set sterilizer features.

User Admin allows you to add, delete, or modify operator identifications, passwords, and access levels.

Cassette Functions allows you to automatically dispose a cassette into the collection box or perform the peroxide clearance procedure.

Network allows you to configure a network connection.

Diagnostics starts a sequence of operator-assisted diagnostic tests and prints a diagnostic test report.

Service Functions are reserved for use by ASP Service Representatives.

File Management allows you to select, display, and print files.

Upload file reads the load items database file from a USB memory stick.

Input/Output door open opens the door on the input or output side.

Input/Output door close closes the door on the input or output side.

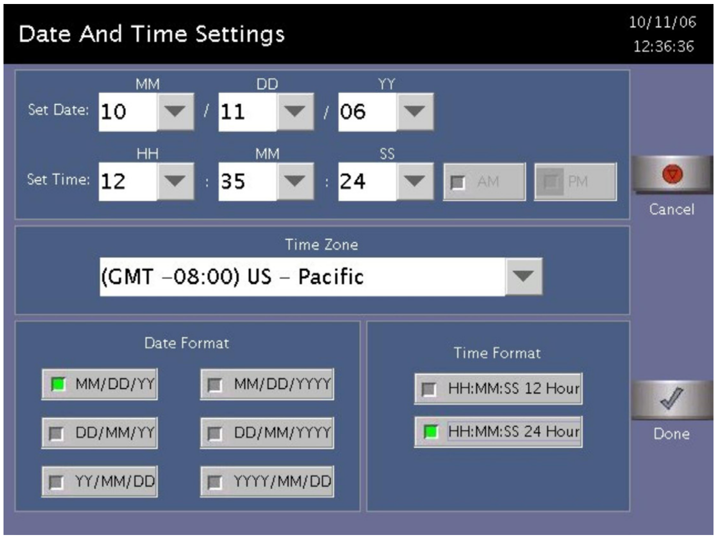
PCMCIA allows you to safely remove the PCMCIA card. Do not try to remove the PCMCIA card without using this feature.

Product Options allows you to enable or disable certain feature upgrades.

The **Back** button returns you to the prior screen from which you originally selected the Additional Utilities Menu screen.

Date and Time Settings

Use the Date and Time Settings screen to set the date and time, and select the local time zone and display formats.



Date And Time Settings

10/11/06
12:36:36

Set Date: MM 10 / DD 11 / YY 06

Set Time: HH 12 : MM 35 : SS 24 ☐ AM ☐ PM

Time Zone: (GMT –08:00) US – Pacific

Date Format:
- ☑ MM/DD/YY
- ☐ MM/DD/YYYY
- ☐ DD/MM/YY
- ☐ DD/MM/YYYY
- ☐ YY/MM/DD
- ☐ YYYY/MM/DD

Time Format:
- ☐ HH:MM:SS 12 Hour
- ☑ HH:MM:SS 24 Hour

Figure 40. Date and Time Setting.

Set Date

Use the MM box to set the month (01-12), the DD box to set the day (01-31), and the YY box to set the year.

Set Time

Use the HH box to set the hour (01-12 if 12-hour format is selected, 00-23 if 24-hour format is selected). Use the MM box to set the minute (00-59) and the SS box to set the second (00-59). If 12-hour format is selected, you may only select hours 01-12, and you must touch the **AM** or **PM** buttons to indicate the correct time.

Time Zone

Scroll through the selections until your time zone is displayed.

Date Format

Select the desired format for the date. The formats that include “YYYY” display a four-digit year.

Time Format

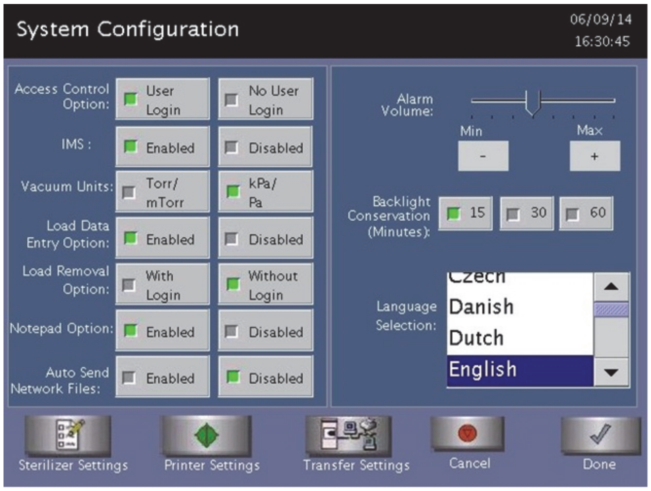
Select 12-hour or 24-hour format. If 12-hour format is selected, the **AM** and **PM** buttons on the **Set Time** line are enabled. If 24-hour format is selected, the **AM** and **PM** buttons are disabled.

Cancel/Done

To cancel the date or time setting, touch the **Cancel** button. When the date and time settings are correct, touch the **Done** button to return to the Additional Utilities menu.

System Configuration

Use the System Configuration screen to set sterilizer features. Selections on this screen allow you to set the volume of the alarm loudspeaker, the language used in displays and reports, and several access, report, and connection features. The sterilizer comes configured with factory-set defaults. If you want to change the default settings, select your preferred settings.



System Configuration 06/09/14 16:30:45

Access Control Option: ☑ User Login ☐ No User Login

IMS : ☑ Enabled ☐ Disabled

Vacuum Units: ☐ Torr/ mTorr ☑ kPa/ Pa

Load Data Entry Option: ☑ Enabled ☐ Disabled

Load Removal Option: ☐ With Login ☑ Without Login

Notepad Option: ☑ Enabled ☐ Disabled

Auto Send Network Files: ☐ Enabled ☑ Disabled

Backlight Conservation (Minutes): ☑ 15 ☐ 30 ☐ 60

Language Selection: Czech, Danish, Dutch, English (selected)

Figure 41. System Configuration.

Access Control Option

User Login requires that a user identification and password be entered before the sterilizer can be loaded and run. This is the factory default setting.

No User Login allows any person to operate the sterilizer.

IMS

Enabled causes the system to capture data with an IMS system (optional).

Disabled causes the system to not capture data with an IMS system (optional).

Vacuum Units

Torr/mTorr expresses vacuum measurements in torr and mtorr.

kPa/Pa expresses vacuum measurements in kilopascals and Pascals. This is the factory default setting.

Load Data Entry Option

Enabled causes the Enter Load Item Data screen to be displayed after login. This is the factory default setting.

Disabled skips the Enter Load Item Data screen.

Load Removal Option

With Login requires that a user enter a user identification and password to open the sterilizer door when a cycle is complete.

Without Login allows any person to open the sterilizer door when a cycle is complete. This is the factory default setting.

Notepad Option

Enabled causes the Cycle Notes screen to be displayed after login. This is the factory default setting.

Disabled skips the Cycle Notes screen.

Auto Send Network Files

Enabled allows the sterilizer to transmit data on a network at the end of a cycle.

Disabled suspends the automatic transmission of network data at the end of a cycle. This is the factory default setting.

Alarm Volume

Touch the + or - buttons to adjust the volume of the alarm loudspeaker.

The factory default setting is in the middle of the scale.

Backlight Conservation (Minutes)

Touch the number of minutes; 15, 30, or 60, to indicate how long the splash screen remains visible in the idle state before starting screen saver mode.

Language Selection

Scroll through the list to select the language used in displays and printed reports. The factory default setting is English.

Sterilizer Settings

Touch Sterilizer Settings to display the following screen. The information entered here is included in the printout, but its use is optional. Touch **Done** to save the settings and return to the previous screen.

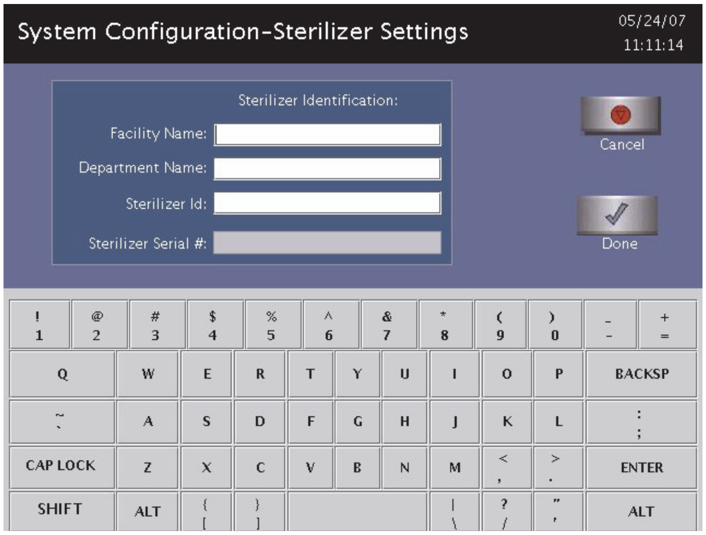

System Configuration-Sterilizer Settings
05/24/07
11:11:14
Sterilizer Identification:
Facility Name:
Department Name:
Sterilizer Id:
Sterilizer Serial #:
Cancel
Done
! 1 @ 2 # 3 $ 4 % 5 ^ 6 & 7 * 8 (9) 0 _ - + =
Q W E R T Y U I O P BACKSP
~ ` A S D F G H J K L : ;
CAP LOCK Z X C V B N M < , > . ENTER
SHIFT ALT { [}] | \ ? / " ' ALT

Figure 42. Sterilizer Settings.

Facility Name – Enter the name of the hospital or medical facility.

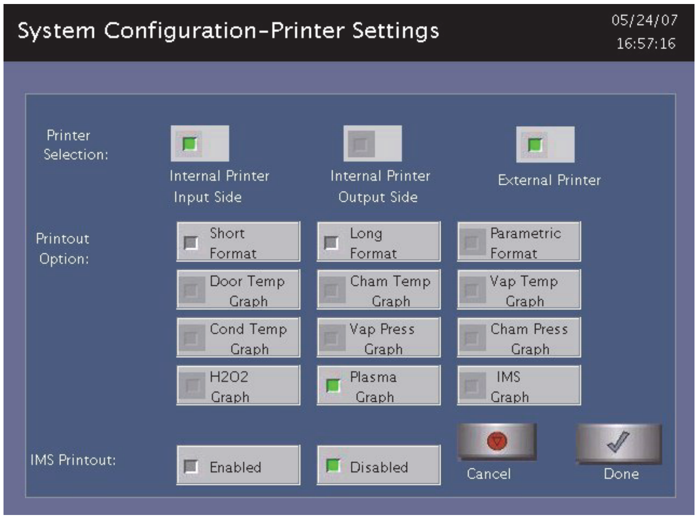
Department Name – Enter the name of the department you wish to use as an identifier for the sterilizer.

Sterilizer ID – Enter an ID such as an asset tag number or other information used to identify the sterilizer.

Sterilizer Serial Number – This is configured by the manufacturer and cannot be altered.

Printer Settings

Touch **Printer Settings** to display the following screen: Touch **Done** to save the changes.



System Configuration-Printer Settings 05/24/07 16:57:16

Printer Selection: ☑ Internal Printer Input Side ☐ Internal Printer Output Side ☑ External Printer

Printout Option: ☐ Short Format ☐ Long Format ☐ Parametric Format ☐ Door Temp Graph ☐ Cham Temp Graph ☐ Vap Temp Graph ☐ Cond Temp Graph ☐ Vap Press Graph ☐ Cham Press Graph ☐ H2O2 Graph ☑ Plasma Graph ☐ IMS Graph

IMS Printout: ☐ Enabled ☑ Disabled

Figure 43. Printer Settings.

Internal Printer Input Side allows you to select the printer on the input side. This is the default.

Internal Printer Output Side allows you to select the printer on the output side (2 door configuration).

External Printer allows you to select an external printer connected to the USB port.

Short Format instructs the sterilizer to print only the short report when a cycle is complete. This is the factory default setting.

Long Format instructs the sterilizer to print only the long report when a cycle is complete.

Parametric Format instructs the sterilizer to print only the parametric report when the cycle is complete. This format is available only when an external printer is selected.

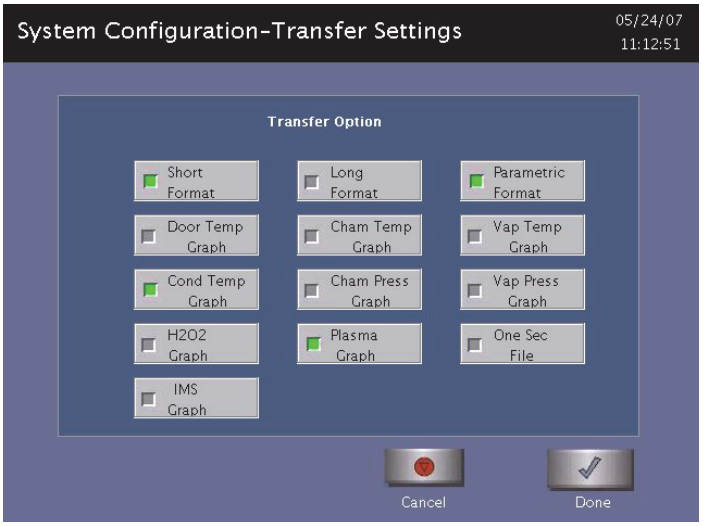
Graphs of various functions are available for printing if an external printer is selected. Touch the graph(s) desired.

IMS Printout Enabled prints the IMS information if an external printer is selected.

IMS Printout Disabled does not print the IMS information.

Transfer Settings

When you touch **Transfer Settings** from the System Configuration menu, the following screen appears. This screen displays selectable report types that automatically transfer via a network to a remote PC upon cycle completion. Touch **Done** to save the settings. Touch **Cancel** to return to the previous screen.



System Configuration-Transfer Settings

05/24/07
11:12:51

Transfer Option

☑ Short Format
☐ Long Format
☑ Parametric Format
☐ Door Temp Graph
☐ Cham Temp Graph
☐ Vap Temp Graph
☑ Cond Temp Graph
☐ Cham Press Graph
☐ Vap Press Graph
☐ H2O2 Graph
☑ Plasma Graph
☐ One Sec File
☐ IMS Graph

Figure 44. Transfer Settings.

Cancel/Done

To cancel system configuration (on the System Configuration Menu), touch the **Cancel** button. When the system configuration settings are correct, touch **Done**. Cancel and Done have the same function on all the other screens you can access through the System Configuration menu.

User Administration

Use the User Administration screen to add, modify, or delete user names, passwords, and access levels. A button on this screen allows you to upload user information from a USB memory stick. Supervisor-level access allows you to add, edit or delete a User or another Supervisor.

✓ ***Note:*** *It is very important that you, as an administrator, keep track of your password. If you forget or lose your password, a service call is necessary for you to regain access to the supervisor area of the system.*

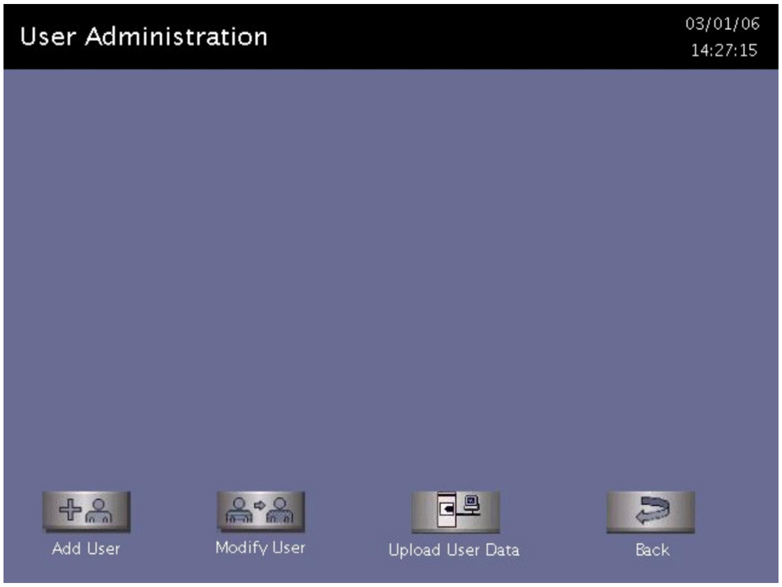


Figure 45. User Administration.

Add User displays the Add User screen. On this screen you can set up a new user’s operator identification, password, and access level.

Modify User displays the Modify User screen. On this screen you can modify or delete an existing user’s identification, password, and access level. Touch **Edit User** on this screen to change information.

Upload User Data causes the sterilizer to receive a complete database file of user names, passwords, and access levels from a USB memory stick.

Back returns you to the Additional Utilities Menu.

Add User

Use the Add User screen to enter a new user's identification, password, and access level.

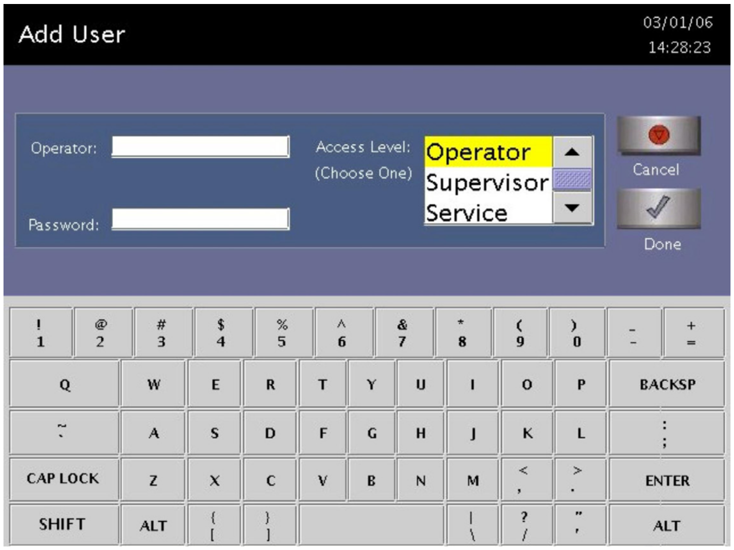

Add User
03/01/06
14:28:23
Operator:
Password:
Access Level:
(Choose One)
Operator
Supervisor
Service
Cancel
Done
! 1 @ 2 # 3 $ 4 % 5 ^ 6 & 7 * 8 (9) 0 _ - + =
Q W E R T Y U I O P BACKSP
~ ` A S D F G H J K L : ;
CAP LOCK Z X C V B N M < , > . ENTER
SHIFT ALT { [}] | \ ? / " ' ALT

Figure 46. Add User.

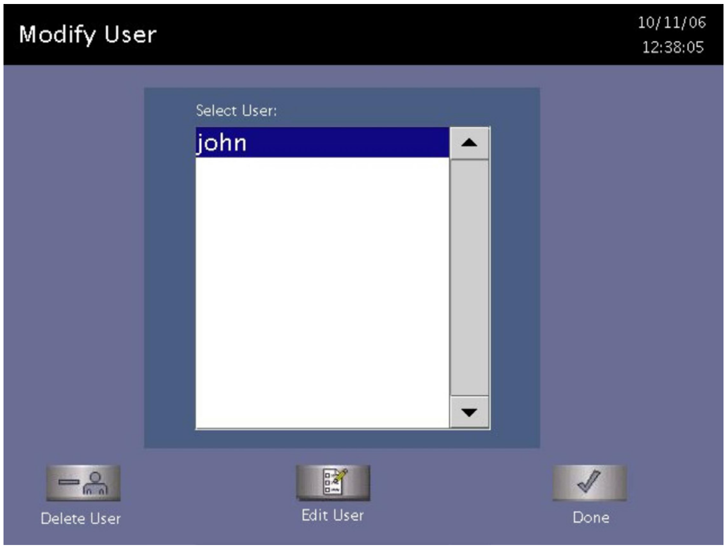
1. Enter the user's operator "identification" in the **Operator** field. The entry must be alpha-numeric and no more than 10 characters.

   ✓ ***Note:*** *Operator and Password fields are case-sensitive.*

2. Enter the user's password in the **Password** field. The entry must be alphanumeric, no more than 10 characters.
3. Scroll through the **Access Level** selections and select an appropriate access level. You may only choose "Operator" or "Supervisor." Only Service Users can select "Service" level access.
4. Touch the **Cancel** button to exit this screen and return to the User Administration screen.
5. Touch the **Done** button when you have finished entering information for a new user.

Modify User

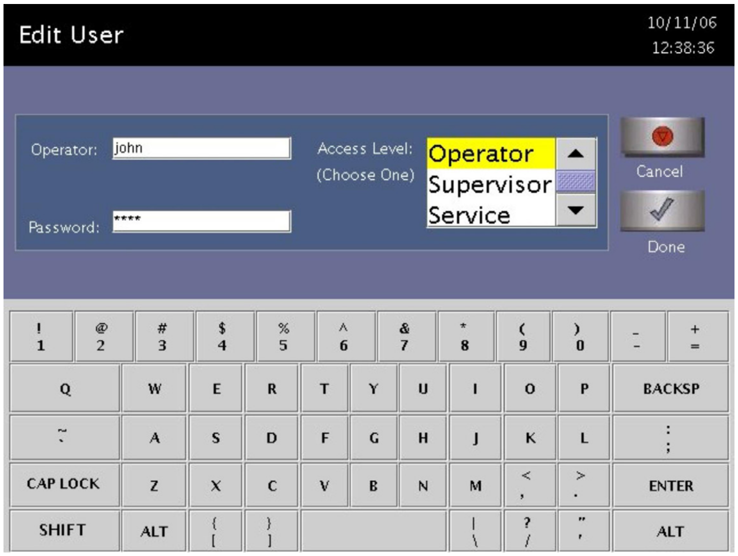
Use the Modify User screen to modify an existing user’s identification, password, and access level.


Modify User
10/11/06
12:38:05
Select User:
Delete User
Edit User
Done

Select User: john

Figure 47. Modify User.

1. Touch the user’s name whose information you wish to edit or delete.
2. Touch **Delete User** to remove the user from the access list and revoke access to sterilizer operation.
3. Touch **Edit User** to change the user’s information including access level.
4. Touch **Done** to return to the previous screen.


Edit User
10/11/06
12:38:36
Access Level:
(Choose One)
Operator
Supervisor
Service
Cancel
Done
! 1 @ 2 # 3 $ 4 % 5 ^ 6 & 7 * 8 (9) 0 _ - + =
Q W E R T Y U I O P BACKSP
~ ` A S D F G H J K L : ;
CAP LOCK Z X C V B N M < , > . ENTER
SHIFT ALT { [}] | \ ? / " ' ALT

Operator: john

Password: ****

Access Level: Operator

Figure 48. Edit User.

- To modify the selected user’s information, touch the **Edit User** button.
- To change the user’s operator name, make changes in the **Operator** field.
- To change the user’s password, make changes in the **Password** field.
- To change the user’s access level, select the desired **Access Level**. You may only choose “Operator” or “Supervisor.” Only Service Users can select “Service” level access.

5. Touch the **Cancel** button to exit this screen and return to the Modify User screen.
6. Touch the **Done** button when you have finished – the Modify User screen is displayed.

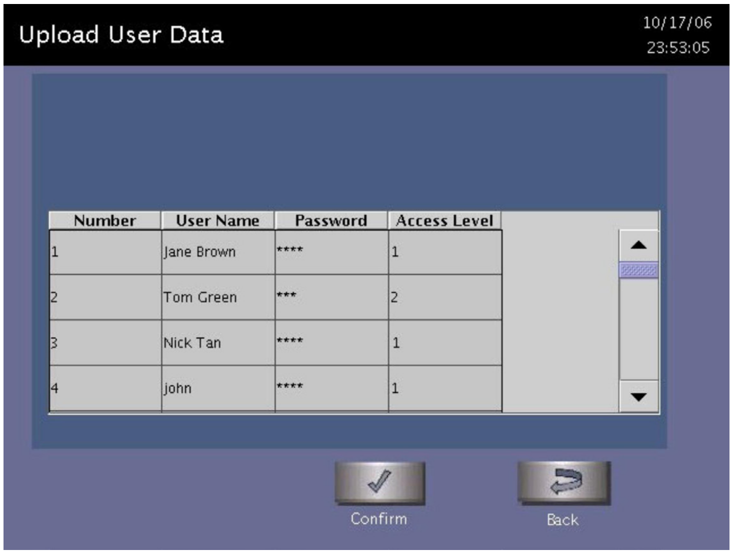
Upload User Data

You can also add up to 1000 user identifications by uploading them to the sterilizer from a USB memory stick.

The user data must be formatted to be compatible with the

STERRAD® 100NX® Database format for user information. It must include the Access Level.

When the **Upload User Data** button is touched, the Upload User Data screen is displayed.



Number	User Name	Password	Access Level
1	Jane Brown	****	1
2	Tom Green	***	2
3	Nick Tan	****	1
4	john	****	1

Figure 49. Upload User Data.

If the user data shown is acceptable, touch **Confirm**. The following section contains information on uploading user data.

Steps to Upload a User Database

To upload a list of user identifications and passwords, perform the following steps:

1. Create an ASCII text file called "**users.rec**" that contains the user identifications, passwords, and access levels. Use Microsoft Notepad to create the entry. Save the file as "users.rec" and in the "Encoding" drop down menu in Notepad Save, select UTF-8. Each entry should be separated by a comma only (no spaces). Example:

```
USERNAME1,PASSWORD1,ACCESS-LEVEL1
USERNAME2,PASSWORD2,ACCESS-LEVEL2
```

where:

- **USERNAME** must be alpha-numeric, no more than 10 characters
- **PASSWORD** must be alpha-numeric, no more than 10 characters
- **ACCESS-LEVEL** must be either 1, 2 (1=Operator, 2 = Supervisor)

2. Copy users.rec file to a USB memory stick and insert the memory stick into the sterilizer's port located on the lower right (your right) side of the sterilizer.
3. On the sterilizer, touch the **Upload User Data** button. The information in the file will be displayed with the password concealed by "*" characters.

   You will receive an "INVALID STERRAD® 100NX® DATABASE FILE" message if the password or user name is longer than the permissible length, you have specified an invalid access level, or you have used an invalid format.
4. Touch **Confirm** to accept the displayed data, logout the current user and return to the prior screen.

Cassette Functions

WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.

Wear chemical resistant latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation or a new or used cassette. Hydrogen peroxide liquid may be present on the cassette, the load or in the chamber.

This function has two options: **Dispose Cassette** which is used to remove the currently loaded cassette from the sterilizer to resolve an error message or to move a cassette that may be stuck in place; and **Peroxide Clearance** which is used to dispose of peroxide remaining in the sterilizer reservoir when the peroxide has expired. Peroxide in the system expires after 10 days. The system displays a message indicating that either of these functions need to be performed.

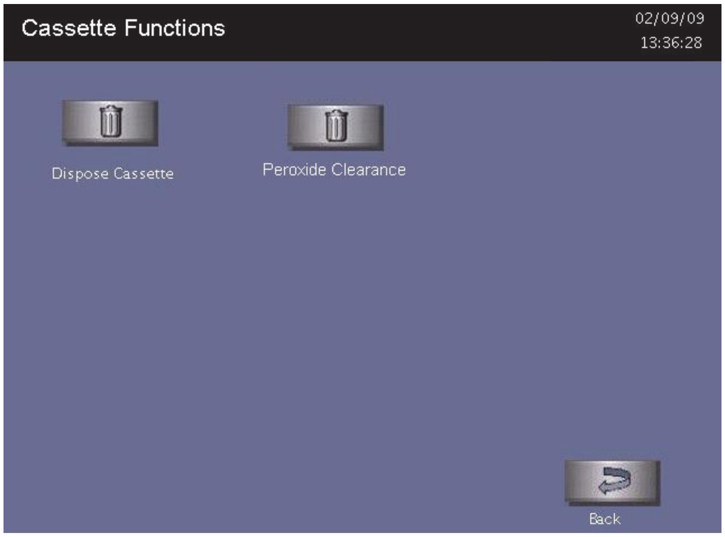
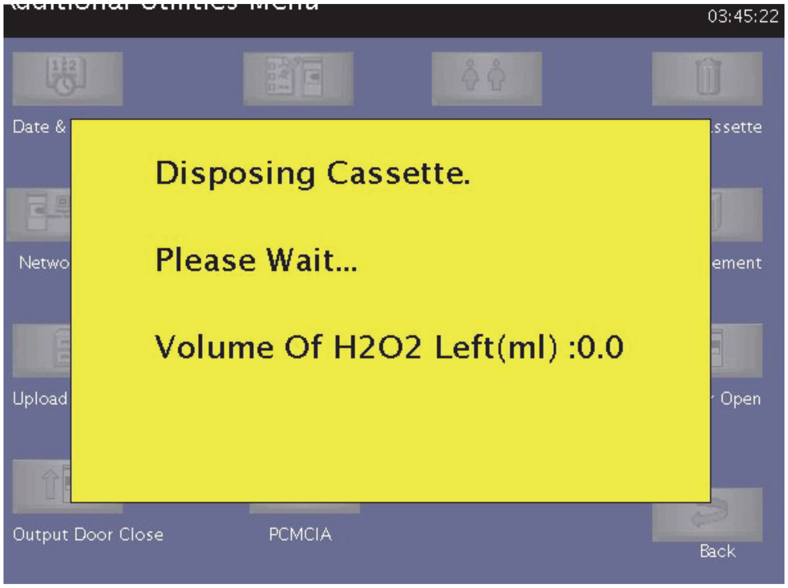


Figure 50. Touch Cassette Functions to display this screen. Touch Dispose Cassette or Peroxide Clearance.

Dispose Cassette

The Dispose Cassette function moves the cassette from inside the sterilizer to the cassette box. The remaining volume of hydrogen peroxide is displayed on the screen.

Touch **Dispose Cassette** to move the cassette into the cassette disposal box.


03:45:22
Date &
ssette
Netwo
ement
Upload
Open
Output Door Close
PCMCIA
Back

Disposing Cassette.

Please Wait...

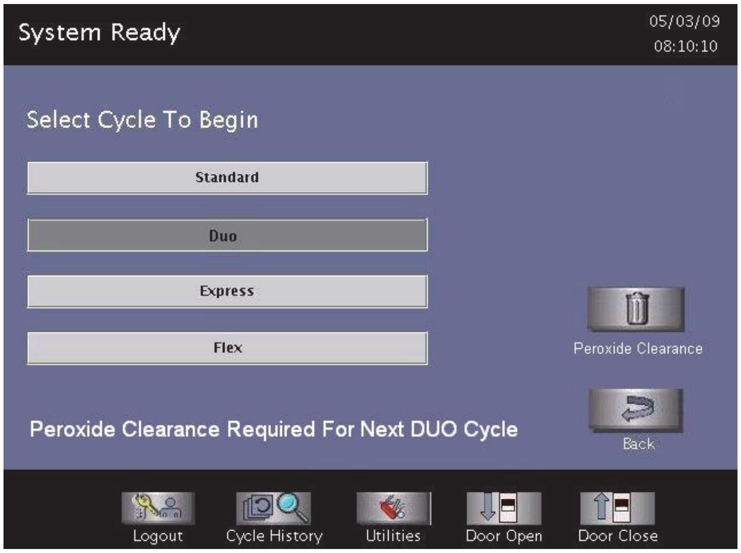
Volume Of H2O2 Left(ml) :0.0

Figure 51. Press Dispose Cassette to Move the Cassette Into the Cassette Disposal Box.

Peroxide Clearance

The DUO Cycle requires the sterilizer to hold peroxide in a reservoir to optimize sterilization. If this peroxide expires, you must dispose of the peroxide remaining in the system. “Peroxide Clearance,” must be performed when a message appears or no subsequent DUO cycles can be run.

✓ ***Note:*** *Before you start Peroxide Clearance, ensure the chamber is empty.*


System Ready

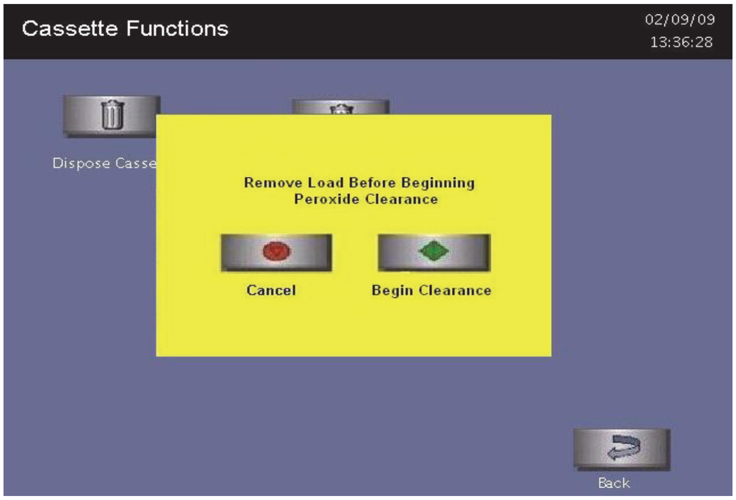
05/03/09
08:10:10

Select Cycle To Begin

Peroxide Clearance Required For Next DUO Cycle

Standard
Duo
Express
Flex
Peroxide Clearance
Back
Logout
Cycle History
Utilities
Door Open
Door Close

Figure 52. Typical Peroxide Clearance Message.


Cassette Functions

02/09/09
13:36:28

Remove Load Before Beginning
Peroxide Clearance

Dispose Casse
Cancel
Begin Clearance
Back

Figure 53. Touch Peroxide Clearance to begin the procedure.

Network

STERRAD® 100NX® Sterilizer can be configured to communicate with a remote personal computer over a network. If you need to use this feature, please contact Advanced Sterilization Products for details on performing this setup. Refer to the User's Network Connection Information Guide found in Appendix C.

Diagnostics

The diagnostics function prompts you to select one of two types of tests (either **Temperature Test** or **Other Tests**). If **Other Tests** is selected, the sterilizer runs ten operator-assisted tests of the sterilizer subsystems. You may skip one or more tests in the automatic sequence by touching the **Cancel** button when a test begins. This causes the program to advance to the next test in the sequence.

The ten tests and the sterilizer elements that are tested are listed in the order in which they occur in the following table.

Touch the **Diagnostics** button to start automatic diagnostic testing of the sterilizer.

✓ ***Note:*** *The duration of the Temperature Test is a minimum of 11 minutes.*

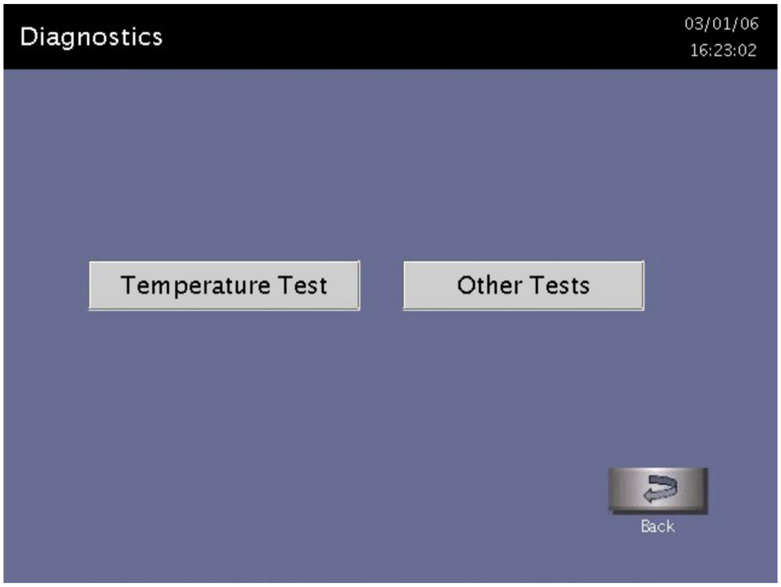


Figure 54. Touch Either Button to Run Tests Than Can Help You Resolve System Messages.

Diagnostic Tests

Order	Test Name	What is tested	Average Time to Run*
1	Power Supply Test	DC power supply	30 sec.
2	Vacuum Test	Vacuum pump, pressure sensors and valves (vacuum control, vent, inlet, transition, delivery, and oil return)	12 min.
3	Door Test	Door Motor and sensors	20 sec.
4	Plasma Test	Plasma electrical subsystem Electrode integrity	3 min. 20 sec.
5	Cassette Test	Cassette electro-mechanical subsystem RFID Reader	5 min.
6	H_2O_2 Sensor Test	Ultraviolet lamp and detector	20 sec.
7	Display Test	Touch screen and display function	20 sec
8	Printer Test	Printer function	10 sec.
9	Fan Test	Fan function	10 sec.
10	Sound Test	Loudspeaker function and volume	1 min.

* Times are approximate. If a failure is detected, the time may be extended.

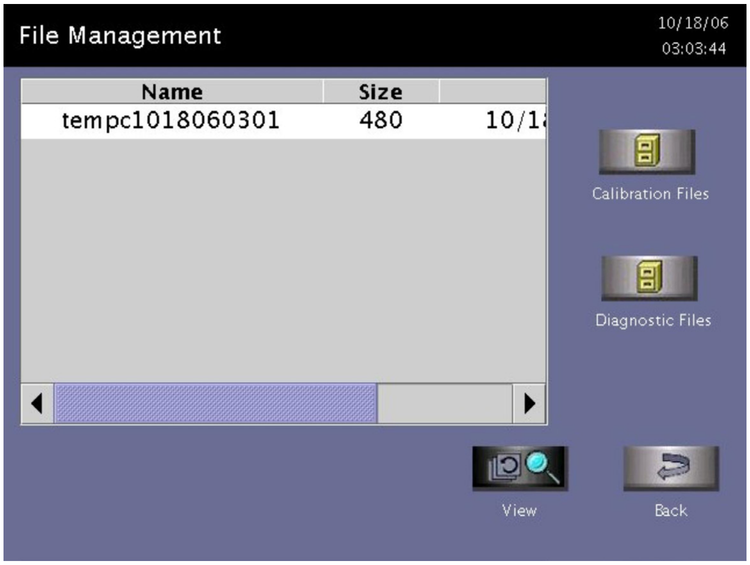
The ten tests take approximately 23 minutes and 10 seconds to complete. When the series of tests is complete, the sterilizer creates and stores a diagnostics file and prints a report. When printing is complete, the Additional Utilities menu is displayed.

Service Functions

The **Service Functions** button is reserved for use by ASP Service Representatives.

File Management

Use the File Management screen to select and display calibration files or diagnostic report files.



Name	Size	
tempc1018060301	480	10/1

Figure 55. File Management.

Calibration Files

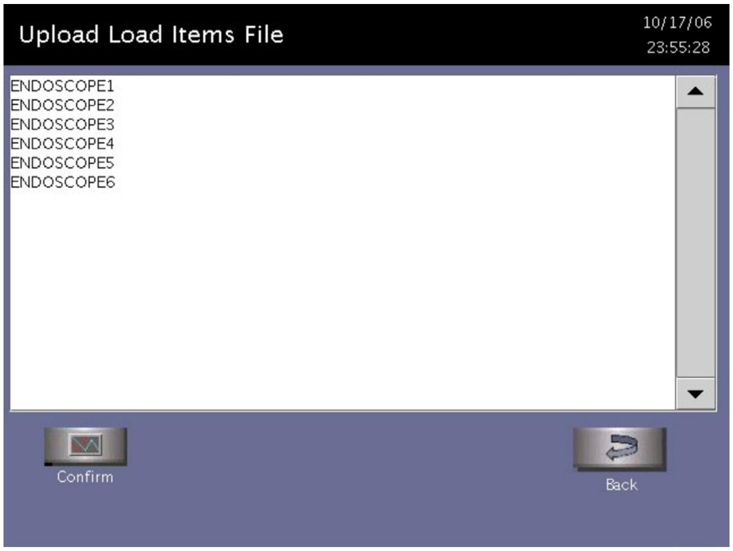
Touch the **Calibration Files** button to display a list of calibration files created during a sterilizer calibration. Scroll through the list and touch the file name you wish to view. Touch the **View** button to display the selected calibration file. Touch the **Back** button to return to the Additional Utilities menu.

Diagnostic Files

Touch the **Diagnostic Files** button to display a list of reports created by the Diagnostics function. Scroll through the list and touch the report you wish to view. Touch the **View** button to display the selected report. Touch the **Back** button to return to the Additional Utilities menu.

Upload File

This screen allows you to upload item information from a separate database to the sterilizer using the USB memory port.



ENDOSCOPE1
ENDOSCOPE2
ENDOSCOPE3
ENDOSCOPE4
ENDOSCOPE5
ENDOSCOPE6

Figure 56. Load Items Files.

1. Using Microsoft "Notepad," create a list of load items similar to the example shown in the figure. To obtain the above display; i.e., ENDOSCOPE1, ENDOSCOPE2, etc. Each load item must be entered on the same line separated by a comma with no spaces before or after the comma. Be sure to include a comma after the last load item. Up to 1000 load items can be defined.
2. Save the file with the file name "loaditems.txt" and use the "encoding" drop down in Notepad to save the file encoded as UTF-8.
3. Insert the USB memory stick with the file loaditems.txt resident on the stick into the sterilizer's USB port located on the lower right side of the front panel.
4. Select "Upload File" for the Additional Utilities men.
5. Review the database displayed on the screen and press **Confirm** to accept the database into the sterilizer or press **Back** to cancel.

Input/Output Doors

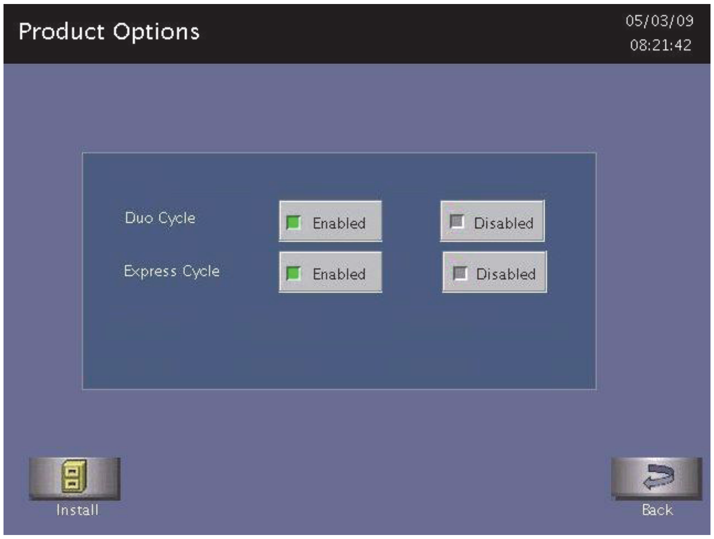
The doors can be opened or closed via the foot pad that you tap with your foot or by touching the **Input** or **Output Door** buttons. If the system has only one door, only the **Input Close Door** and **Input Open Door** buttons are available for use. Only one door can be opened at a time. For example, if the Input Door is open, the Output Door cannot be opened at the same time.

The **Input Open Door** and **Input Close Door** buttons open and close the input side of the sterilizer. That is the side where you load your instruments for processing.

The **Output Open Door** and **Output Close Door** buttons open and close the output or clean side of the sterilizer. This is the side, on a two door unit, where you would remove your sterilized items. When the door is moving, the door open and close buttons, and the foot pad, are disabled until the door has completed its movement.

Product Options

When you select Product Options from the Additional Utilities Menu, and the EXPRESS or DUO cycles are installed, the following is displayed after the installation is complete, and every time you select Product Options after installation. ENABLED is the default option. This feature is only available with Supervisor-Level access.


Product Options

05/03/09
08:21:42

Duo Cycle ☑ Enabled ☐ Disabled

Express Cycle ☑ Enabled ☐ Disabled

Figure 57. Product Options.

Install guides you to install any newly purchased features.

Back returns you to the Additional Utilities Menu.

Enabled displays any cycle in your sterilizer which can be selected (enabled). The choices appear on the Start Cycle display.

Disabled removes the selected cycle buttons from the Start Cycle Screen. These cycles are still available for future use by selecting Enabled on the Product Options screen.

Appendix A.

Sterilizer Specifications

Power	The phase rotation is adjusted to match the system requirements at installation. **208V 60 Hz Power:** For versions employing 208V, 60 Hz power, the sterilizer requires a NEMA L21-30 five-wire grounding twist lock outlet attached to a dedicated 30 Amp 3 phase 208 Volt circuit with separate neutral and ground conductors. **380 – 415V 50/60 Hz Power:** The sterilizer requires a five-wire grounding outlet attached to a dedicated 30 AMP, 3 phase, (200 – 240VAC, 380 – 415V) ±10%, 50/60 Hz ±5% circuit with separate neutral and ground conductors. **200V 50/60 Hz Power (Japan):** The sterilizer requires a four-wire Delta configuration to a dedicated 30 AMP circuit.
Dimensions	H: 70.5 in. (179.1 cm), W: 30.5 in. (77.5 cm), D: 40 in. (102 cm).
Service clearances	Front: 39.5 in. (100 cm); Back: 39.5 in (100 cm); Top: 39.5 in. (100 cm) Left side: 39.5 in. (100 cm); Right side: 39.5 in. (100 cm).
Weight	425 kg, 938 lbs 1-Door system 457 kg, 1,006 lbs 2-Door system
Chamber volume	152 liters.W20.7 in. (51 cm), H16.1 in. (41 cm), D28.93 in. (73.5 cm). Usable volume: 93.4 liters (3.3 cubic feet)
Chamber shelves	Two shelves, W 17 in. (42.5 cm), D 28 in. (70 cm). Shelf capacity: 55 lb. (25 kg) uniformly distributed. Both shelves are removable.
Temperature	Operating: 18°C – 35 °C (64° – 95°F). Storage: -29°C – 70°C (-20°F – 158°F)

Humidity	Operating: 10% – 85% up to 30ºC. Linearly decreasing from 85% at 30ºC to 70% at 40ºC non-condensing Storage: 10% – 100% (rainfall will be permitted).
Altitude/Pressure	Operating altitude up to 3095 m (10,152 ft.). Atmospheric pressure 520 – 775 torr
Cycle temperature	47°C – 56°C (116.6°F – 132.8°F)
Cycle time	STANDARD Cycle - 47 minutes DUO Cycle - 60 minutes EXPRESS Cycle - 24 minutes FLEX Cycle - 42 minutes
Connectors	Network: RJ45; Barcode reader: USB. Printer: USB
Main Power Cable	12 AWG (4 mm^2), 3 m (9.84 feet) long, 5 conductors NEMA L21 - 30P (USA and Canada.) Each country is responsible for installing an appropriate 3 phase plug according to their facility's power requirements. The plug must match the phase rotation.
Mobility	On wheels
Venting Requirements	None required
Gas Tank Requirements	None required
Heat Generation	Idle: 289 BTU/hour In operation: 8,189 BTU/hour maximum
RF Generation	Portable and mobile RF communications equipment can affect medical Electrical Equipment.

Medical Device Requirements and Guidelines	Medical Device Directive 2007/47/EC
	IEC/EN 61010-1: Safety Requirements For Electrical Equipment For Measurement, Control, And Laboratory Use – Part 1: General Requirements
	EN 61010-2-040: Safety Requirements for Electrical Equipment, Control and laboratory Use. Particular requirements for sterilizer and washer-disinfectors used to treat medical devices.
	IEC 60601-1: Medical Electrical Equipment – Part 1: General Requirements For Safety (Japan Requirement)
	EN 60601-1-2: Medical Electrical Equipment - electromagnetic Compatibility - Requirements and Tests.
	ANSI/AAMI/ISO 14937: Sterilization Of Health Care Products – General Criteria For Characterization Of A Sterilizing Agent And Development, Validation, And Routine Control Of A Sterilization Process
	CAN/CSA C22.2 No. 61010-1.
	UL 61010-1.
Medical Device Agencies	US: FDA (Food and Drug Administration)
	EU: TUV Product Service (ASP's Notified Body)
	Japan: MHLW (Ministry of Health, Labor and Welfare)
	Canada: TPP (Therapeutic Products Programme)
	Australia: TGA (Therapeutic Goods Administration)

Appendix B.

Consumables, Accessories, and Additional Parts

Consumable Products	Product Code	Description
STERRAD® 100NX® Cassette	10144	2 cassettes per case.
Thermal Printer Paper Roll-Case	10305	Used with the thermal printer to record sterilizer information. 12 rolls/case
Cassette Disposal Box - Case	20227	This box is used to collect cassettes for disposal. 10 boxes/case.
STERRAD® 100NX® EXPRESS Test Pack	20123	Contains the BI and pouch.
STERRAD® 100NX® Test Pack for STANDARD, FLEX and DUO Cycles	20243	Contains the test vials, pouch, mats, and BI.
STERRAD® CYCLESURE® 24 Biological Indicator	14324	Used as a standard method for frequent monitoring of the STERRAD® Sterilizer cycles.
STERRAD® SEALSURE® Chemical Indicator Tape	14202	Used to seal packaged instruments, the tape changes color when exposed to hydrogen peroxide.
STERRAD® Chemical Indicator Strips	14100	Placed inside instrument packages, the chemical indicator strips change color when exposed to hydrogen peroxide.
Tyvek® Pouches and Rolls with STERRAD® Chemical Indicator		Contact your ASP Representative for a complete list of pouches, rolls, instrument trays and accessories.
APTIMAX® Instrument Trays and accessories		Contact your ASP Representative for a complete list of pouches, rolls, instrument trays and accessories.

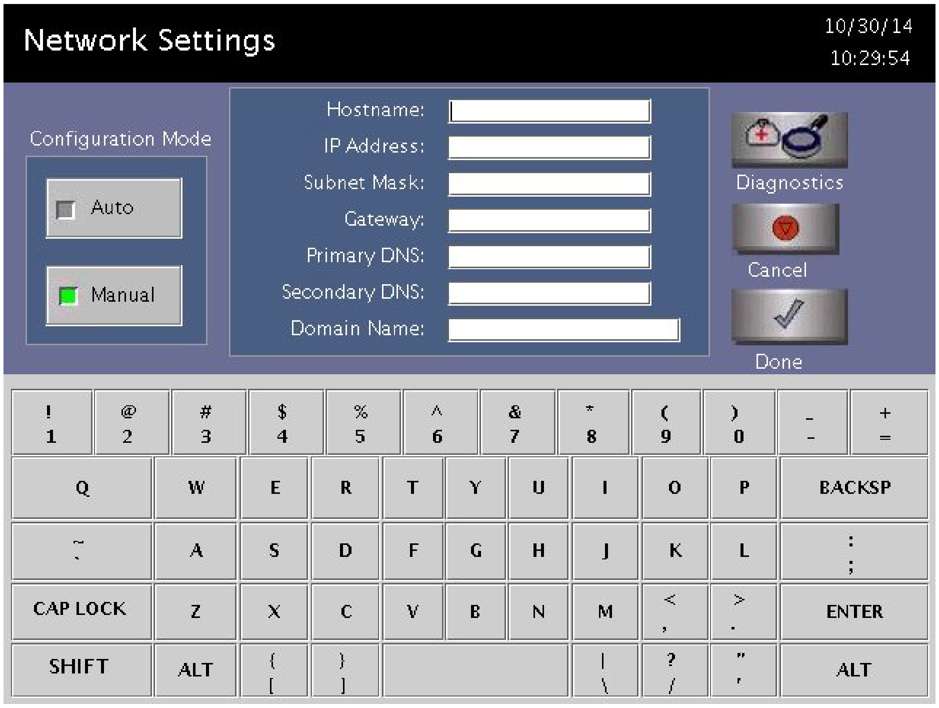
Consumable Products	Product Code	Description
Barcode Reader	11142	Optional barcode scanner for tracking instruments and other information in the cycle history file.
Independent Monitoring System (IMS)	10140	For compliance with ISO 14937. The Independent Monitoring System (IMS) is an optional feature that may be purchased and installed on the sterilizer. It is an independent data collection system that can be used for system validation or requalification. All of the sensors are independent from the system sensors and the data collected from the IMS is identified separately from the system's one-second data

Additional Parts	Part Number
Compact Flash Card and Adapter	04-53004-0-001

ASP offers a comprehensive line of consumables and accessories which have been fully tested and validated for use with the STERRAD® 100NX® Sterilizer. For more information on any of these products, contact your local ASP Representative.

Appendix C.

User's Network Connection Information Guide


Network Settings
10/30/14
10:29:54
Configuration Mode
Auto
Manual
Hostname:
IP Address:
Subnet Mask:
Gateway:
Primary DNS:
Secondary DNS:
Domain Name:
Diagnostics
Cancel
Done
! 1 @ 2 # 3 $ 4 % 5 ^ 6 & 7 * 8 (9) 0 _ - + =
Q W E R T Y U I O P BACKSP
~ ` A S D F G H J K L : ;
CAP LOCK Z X C V B N M < , > . ENTER
SHIFT ALT { [}] | \ ? / " ' ALT

Configuration Mode: ☐ Auto ☑ Manual

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Section 1.

Digital Transfer Interface

This guide is designed for the individuals who are performing and/or overseeing the connection of the STERRAD® 100NX® Sterilizer to a network. This procedure should be done in collaboration with your facility's computer network department.

Service Level Access and a service call by an ASP technician is required to complete the entire networking setup.

Prior to performing any tasks on the sterilizer, you must read the safety information in the STERRAD® 100NX® User's Guide.

✓ ***Note:*** *The STERRAD® 100NX® Digital Transfer Interface (DTI), if it is available on your STERRAD®, is primarily designed for communication with an Instrument Tracking System (ITS). Your ASP technician can provide a list of ASP-qualified ITS providers.*

✓ ***Note:*** *The Health Care Organization should validate the performance of any DTI-ITS system prior to use.*

Network Connection Specifications

The following items are required for Digital Transfer Interface network connection:

- Category 5e or better Ethernet cabling should be utilized for the network connection. A Category 5e cable with a male RJ45 connector must be connected to the network port located on the lower right side of the sterilizer.

  ✓ ***Note:*** *ASP is not responsible for any equipment necessary to support the network connection.*

- Support for Local Area Network (LAN) port speeds of automatic, 100/10 Mbps Ethernet.

- Use of DHCP IP Addressing (“Auto” mode) is highly recommended. Static (“Manual” mode) configuration (IP Address, Subnet Mask, Gateway, Primary Domain Name System (DNS), and Secondary DNS assigned by the Information Technology [IT] department) will also be supported.
- The default Host Name assigned to the sterilizer is “100NX” followed by the sterilizer’s serial number and can be customized. The sterilizer Host Name must be no more than 20 characters long.
- The port speed will be set automatically.
- Microsoft® Distributed File System (DFS) is not supported.
- Customer IT must provide a local user account with full administrator rights on the computer server using any of these Windows® operating systems: Windows XP, Windows 7, Windows Server 2003 or Windows Server 2008 R2. For other versions, please contact your local ASP representative. The account should be authenticated with a password.

  ✓ ***Note:*** *If the password of this local user account expires, the DTI of the sterilizer will not be able to access the shared folders and cycle files will not be transferred correctly. To avoid this issue, hospital IT staff can disable password expiration for this account.*

- Provide one shared folder per connected sterilizer.
- Complete form F-107773 prior to the ASP technician’s installation visit. The completed form contains information needed by the ASP technician for network setup.

Security Reminders

- Your hospital LAN should be isolated (i.e. firewalled, using Virtual LANs [VLANs]) from the public internet.
- Access to your hospital LAN should be controlled physically and logically (e.g., using logins and passwords).
- ASP medical devices do not run Windows Operating Systems (OS) and do not require regular security updates when operated in the intended use environment (a hospital LAN).

For Health Care Facilities:

*The FDA is recommending that you take steps to evaluate your network security and protect your hospital system. In evaluating network security, hospitals and health care facilities should consider:

- Restricting unauthorized access to the network and networked medical devices.
- Keeping appropriate antivirus software and firewalls up-to-date.
- Monitoring network activity for unauthorized use.
- Protecting individual network components through routine and periodic evaluation, including updating security patches and disabling all unnecessary ports and services.
- Contacting the specific device manufacturer if you think you may have a cybersecurity problem related to a medical device. If you are unable to determine the manufacturer or cannot contact the manufacturer, the FDA and DHS ICS-CERT may be able to assist in vulnerability reporting and resolution.
- Developing and evaluating strategies to maintain critical functionality during adverse conditions.

*** "FDA Safety Communication: Cybersecurity for Medical Devices and Hospital Networks." U.S. Food and Drug Administration. June 13, 2013. Web. May 20, 2014.**

If You Have Questions

If you are located in the United States and have questions about the STERRAD® 100NX® Sterilizer, please call ASP Professional Services at 1-888-STERRAD (1-888-783-7723). Internationally, call your local ASP Representative. You may also wish to visit our website at www.aspjj.com.

Section 2.

Setting Up the Network

Network Settings Display

Use the Network Settings screen to configure the sterilizer's network connection.

✓ ***Note:*** *Always check with your facility's Network Administrator before configuring or changing any of the settings on this screen.*

For networks that don't support DHCP, you must select "Manual" (static) configuration.

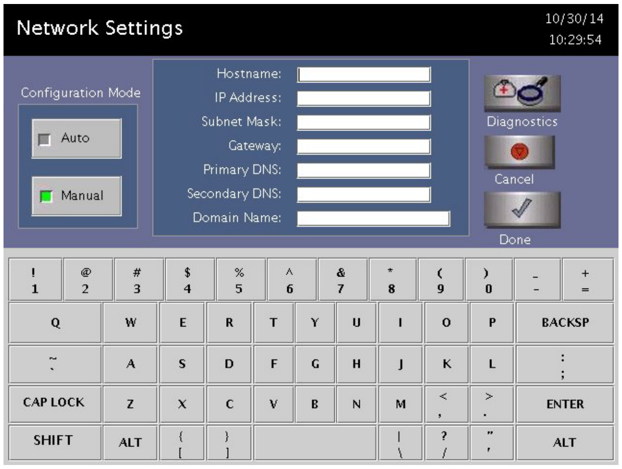

Network Settings
10/30/14
10:29:54
Configuration Mode
Auto
Manual
Hostname:
IP Address:
Subnet Mask:
Gateway:
Primary DNS:
Secondary DNS:
Domain Name:
Diagnostics
Cancel
Done
! 1 @ 2 # 3 $ 4 % 5 ^ 6 & 7 * 8 (9) 0 _ - + =
Q W E R T Y U I O P BACKSP
~ ` A S D F G H J K L : ;
CAP LOCK Z X C V B N M < , > . ENTER
SHIFT ALT { [}] | \ ? / " ' ALT

Figure 58. Network Settings Display.

✓ ***Note:*** *For all Network Setting screens that display a keyboard, the keyboard will be U.S. English characters and format.*

Configuration Mode

Select Auto to configure the IP address dynamically through Dynamic Host Configuration Protocol (DHCP). This is the preferred mode.

Or, Select Manual to configure the IP address manually. Obtain the static IP settings; (e.g., IP Address, Subnet Mask, Gateway, Primary, and Secondary DNS IP addresses) from your Network Administrator.

Refer to the table below for acceptable character use for each parameter.

Parameters	**Acceptable Characters**
Hostname	Alphanumeric and _ (*underscore*)
IP Address Subnet Mask Gateway Primary DNS Secondary DNS	Numeric and . (*period*)
Domain Name	Alphanumeric and - @ < > | ? “ ` _ \ / ‘. , ; : [ ] { } _
Username Password	Alphanumeric and ~ ! @ # $ ^ & ( ) _ { } `- % * = + [ ] ; : “ ‘ . , < > ? / \ |
Shared Folder Name PC Server	Alphanumeric and @ _ ; , . ` [ ] { } | : ; “ ‘ < > ? / \ . , -

Hostname

This is the DNS name of the sterilizer on a network. A Hostname is created by default. To change the default, edit the Hostname field as needed. The Hostname must be a unique name on your local network.

In Manual configuration mode, enter the Hostname assigned to the sterilizer. Obtain this information from your network administrator.

✓ ***Note:*** *The sterilizer will support up to 20 characters maximum.*

IP Address

A 32-bit address used to identify a node on a Transmission Control Protocol/ Internet Protocol (TCP/IP) network. Each node on the IP network must be assigned a unique IP address, which is made up of the network ID, plus a unique host ID. This address is typically represented with the decimal value of four octets separated by a period (for example, 192.168.1.127).

This field cannot be changed in Auto configuration mode.

In Manual configuration mode, enter the static IP Address assigned to the sterilizer. Obtain this information from your network administrator.

Subnet Mask

A 32-bit value that enables the recipient of IP packets to distinguish the network ID and host ID portions of the IP address. For example, subnet masks use the format 255.255.255.0.

This field cannot be changed in Auto configuration mode.

In Manual configuration mode, enter the Subnet Mask information. Obtain this information from your network administrator.

Gateway

A device connected to multiple physical TCP/IP networks capable of routing or delivering IP packets between them. A gateway is also called an IP router.

This field cannot be changed in Auto configuration mode.

In Manual configuration mode, enter the Gateway IP address; (e.g., 192.168.1.1). Obtain this information from your network administrator.

Primary DNS

The IP address of the primary computer running a service that maintains information about a portion of the DNS database and responds to and resolves DNS queries.

This field cannot be changed in Auto configuration mode.

In Manual configuration mode, enter the Primary DNS address (e.g. 192.168.1.5). Obtain this information from your network administrator.

Secondary DNS

The IP address of the secondary computer running a service that maintains information about a portion of the DNS database and responds to and resolves DNS queries. The secondary DNS IP address is optional.

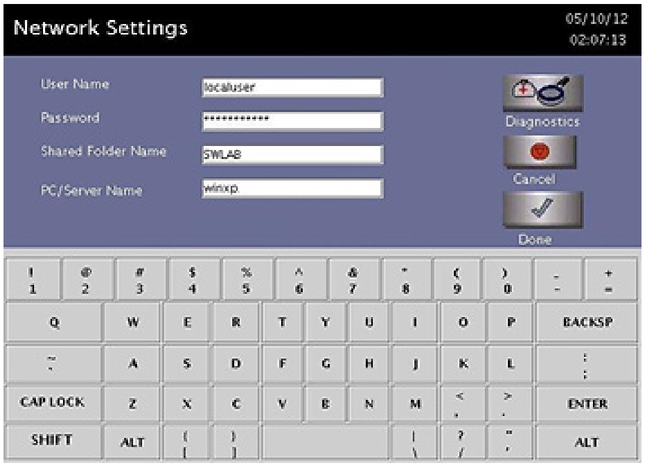
This field cannot be changed in Auto configuration mode.

In Manual configuration mode, enter the Secondary DNS address (e.g. 192.168.1.6). Obtain this information from your network administrator.

Domain Name

This field cannot be changed in Auto configuration mode.

In Manual configuration mode, no entry is required.



Diagnostics
Cancel
Done
! 1 @ 2 # 3 $ 4 % 5 ^ 6 & 7 * 8 (9) 0 _ - + =
Q W E R T Y U I O P BACKSP
~ ` A S D F G H J K L : ;
CAP LOCK Z X C V B N M < , > .
SHIFT ALT { [}] | \ ? / " '
ALT ENTER

Network Settings 05/10/12 02:07:13

User Name: localuser

Password: ***********

Shared Folder Name: SWLAB

PC/Server Name: winxp

Figure 59. Network Settings Display. The data shown in this screen's field is for context.

✓ *Note:* *The sterilizer does not logon to the domain or workgroup*

User Name

Enter the User Name information to login onto the PC or Server. Obtain this information from your network administrator.

✓ ***Note:*** *The sterilizer will support up to 30 characters maximum.*

Password

Enter the Password information to login onto the PC or Server. The password is case sensitive. Obtain this information from the network administrator. If using a facility's password, have their network administrator enter the password in the field.

✓ ***Note:*** *To remove the password from the sterilizer's memory, delete all characters in the entry field and touch* ***Done****.*

✓ ***Note:*** *The sterilizer will support up to 15 characters maximum.*

Shared Folder Name

Enter the name of the shared folder located on the remote PC or Server. The folder must be configured with shared and security permissions.

Obtain this information from your network administrator. One shared folder for each connected sterilizer is required to avoid overwriting existing data files.

✓ ***Note:*** *The sterilizer will support up to 60 characters maximum.*

PC/Server Name

Enter the computer server name. An IP Address may be entered if the remote computer server is assigned a static IP address. Obtain this information from your network administrator. For example, SERVER1.jnj.com.

✓ ***Note:*** *The sterilizer will support up to 20 characters maximum.*

✓ ***Note:*** *Fully Qualified Domain Name (FQDN) will not be supported.*

System Network Setup

✓ ***Note:*** *Supervisor Level Access is required for this procedure.*

These steps are used to configure the network settings on the sterilizer. These steps must be performed before the sterilizer can communicate with a networked PC or server.

Have your network administrator complete form F-107773 before proceeding. All the references to information needed in the Network Setting screen are on the form.

1. Ensure that the Ethernet cable is plugged into the sterilizer and to the active data port on the wall.
2. Navigate to the System Ready screen.

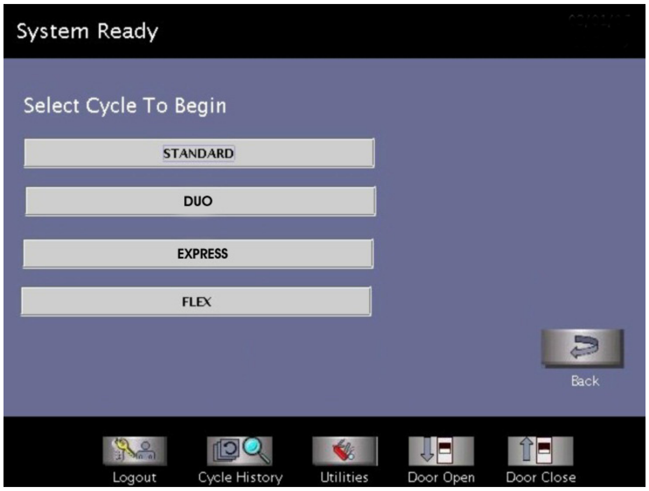

System Ready
Select Cycle To Begin
STANDARD
DUO
EXPRESS
FLEX
Back
Logout
Cycle History
Utilities
Door Open
Door Close

Figure 60. Cycle Selection. Your System May Have Other Cycle Options.

3. Touch **Additional Utilities** on the System Ready screen.
4. Login with Supervisor Level account.

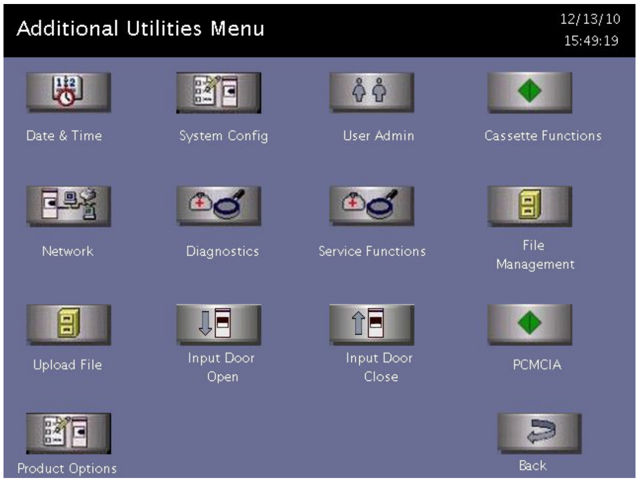
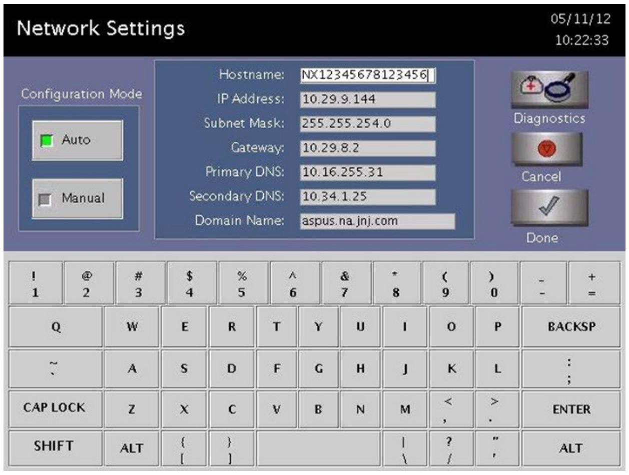

Additional Utilities Menu
12/13/10
15:49:19
Date & Time
System Config
User Admin
Cassette Functions
Network
Diagnostics
Service Functions
File Management
Upload File
Input Door Open
Input Door Close
PCMCIA
Product Options
Back

Figure 61. Additional Utilities Menu. Touch Network.

5. Touch **Network** on the Additional Utilities Menu.



Network Settings

05/11/12
10:22:33

Configuration Mode

☑ Auto

☐ Manual

Hostname: NX12345678123456

IP Address: 10.29.9.144

Subnet Mask: 255.255.254.0

Gateway: 10.29.8.2

Primary DNS: 10.16.255.31

Secondary DNS: 10.34.1.25

Domain Name: aspus.na.jnj.com

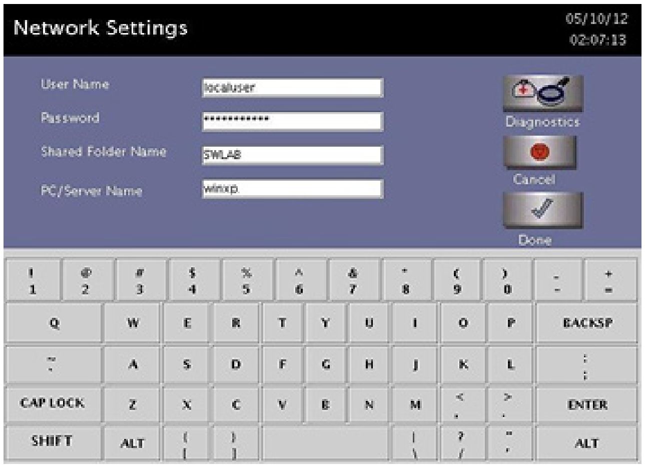
Figure 62. Network Settings 1. The data shown in this screen's field is for context.

Use the completed form F-107773 to complete the setup:

6. Select **Auto** if box 3 is checked. Proceed to step 14.
7. Select **Manual** if box 4 is checked.
8. Enter the information from line 15 for the Hostname
9. Enter the information from line 5 for IP Address.
10. Enter the information from line 6 for Subnet Mask.
11. Enter the information from line 7 for the Gateway.
12. Enter the information from line 8 for the Primary DNS.
13. Enter the information from line 9 for the Secondary DNS.

    ✓ ***Note:*** *If Workgroup/Domain appears on your sterilizer, leave the field blank*

14. Touch **Done**.


Network Settings

05/10/12
02:07:13

User Name: localuser

Password: ************

Shared Folder Name: SWLAB

PC/Server Name: winxp

Diagnostics
Cancel
Done
! 1 @ 2 # 3 $ 4 % 5 ^ 6 & 7 * 8 (9) 0 _ - + =
Q W E R T Y U I O P BACKSP
~ ` A S D F G H J K L : ;
CAP LOCK Z X C V B N M < , > .
ENTER
SHIFT ALT { [}] | \ ? / " '
ALT

Figure 63. Enter Network Settings 2. The data shown in this screen's field is for context.

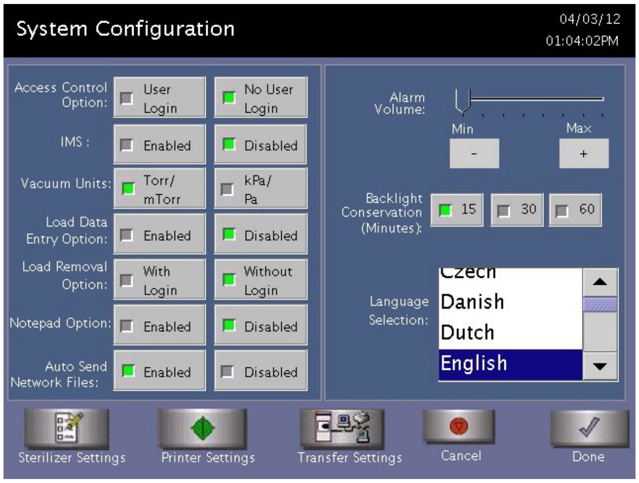
15. Enter the information from line 11 for the User Account (Username).
16. Have the facility's network administrator enter the Password.
17. Enter the information from line 13 for the Shared Folder Name.

✓ ***Note:*** *Using a single shared folder for multiple sterilizers may overwrite existing data. Use a unique shared folder name for each connected STERRAD® 100NX® Sterilizer.*

18. Enter the information from lines 14 for the PC (computer) Server Name.

✓ ***Note:*** *Use an IP Address if the computer server has a static IP address assigned. The sterilizer will lose connectivity to the computer server if the IP address of the computer server changes.*

19. Touch **Done**.
20. Touch **System Config** on the Additional Utilities Menu. The following screen will display.



System Configuration 04/03/12 01:04:02PM

Access Control Option: ☐ User Login ☑ No User Login

IMS : ☐ Enabled ☑ Disabled

Vacuum Units: ☑ Torr/ mTorr ☐ kPa/ Pa

Load Data Entry Option: ☐ Enabled ☑ Disabled

Load Removal Option: ☐ With Login ☑ Without Login

Notepad Option: ☐ Enabled ☑ Disabled

Auto Send Network Files: ☑ Enabled ☐ Disabled

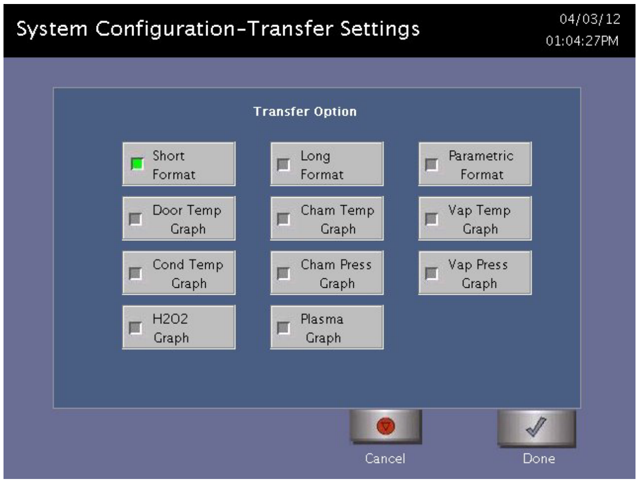
Alarm Volume: Min Max - +

Backlight Conservation (Minutes): ☑ 15 ☐ 30 ☐ 60

Language Selection: Czech, Danish, Dutch, English

Figure 64. System Configuration Screen.

21. For Auto Send Network Files option, select **Enabled**.
22. Touch **Transfer Settings**.



System Configuration-Transfer Settings 04/03/12 01:04:27PM

Transfer Option

☑ Short Format ☐ Long Format ☐ Parametric Format

☐ Door Temp Graph ☐ Cham Temp Graph ☐ Vap Temp Graph

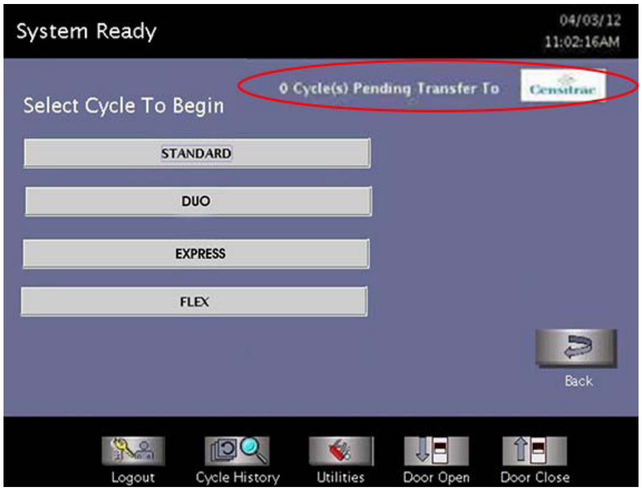
☐ Cond Temp Graph ☐ Cham Press Graph ☐ Vap Press Graph

☐ H2O2 Graph ☐ Plasma Graph

Figure 65. Transfer Settings.

✓ ***Note:*** *If your sterilizer is configured with an Instrument Tracking Software (ITS), a CSV file will be transferred by default. Your screen may be different based on your configuration*

23. Select desired printout format to be transferred to the computer server.
24. Touch **Done**.
25. Touch **Done**.
26. Touch **Back**.


System Ready

04/03/12
11:02:16AM

0 Cycle(s) Pending Transfer To Censitrac

Select Cycle To Begin

Figure 66. System Ready Screen Showing Cycles to be Transferred.

The number of Cycles Pending Transfer is displayed in the upper right of the screen. Up to 200 cycles will be queued if the network connection is lost.

CAUTION!

Under this condition, when the 201st cycle is started, the first cycle data file will be overwritten. Once the network connection has been established or reestablished, the file transmission will resume. When the count of the cycle files pending transfer reaches 10 or greater, notify your network administrator of potential network problems.

✓ ***Note:*** *Always use hardcopy cycle printouts if the network connection is lost or down.*

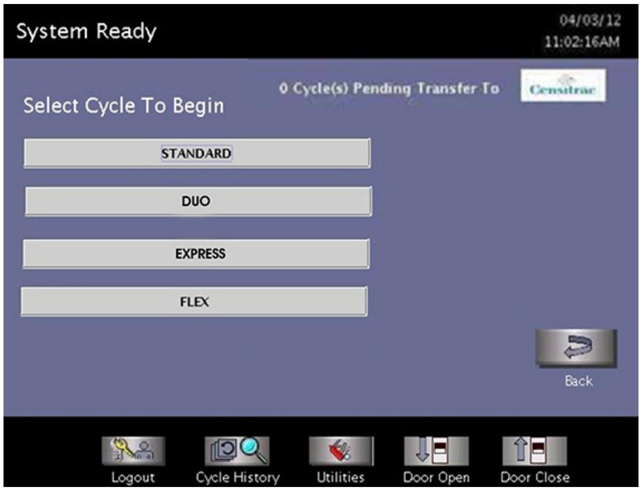
27. To manually transfer a cycle file to test the network connection, see “Manual Network File Transfer”.

Section 3.

Manual Network File Transfer

With the network successfully configured, cycle files can be manually transferred to the computer server.

1. Navigate to the System Ready Screen.



System Ready

04/03/12
11:02:16AM

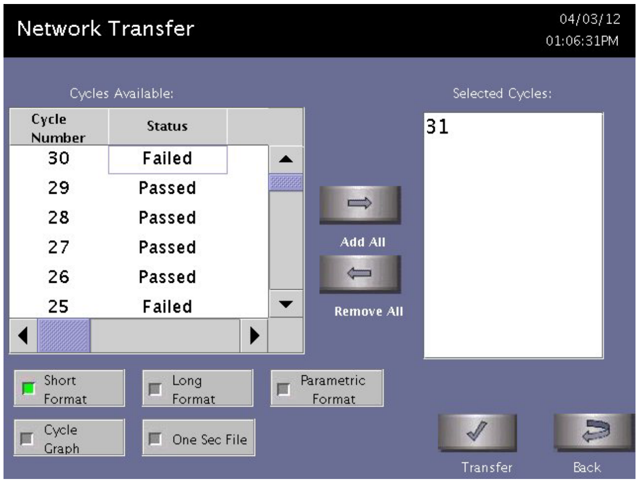
Select Cycle To Begin

0 Cycle(s) Pending Transfer To

Censitrac
STANDARD
DUO
EXPRESS
FLEX
Back
Logout
Cycle History
Utilities
Door Open
Door Close

Figure 67. Cycle Selection.

2. Touch **Cycle History**. The Cycle History screen is displayed.
3. Touch **Data Transfer** on the Cycle History screen.
4. Touch **Network Transfer** and the Network Transfer Screen is displayed.



Network Transfer

04/03/12
01:06:31PM

Cycles Available:

Cycle Number	Status
30	Failed
29	Passed
28	Passed
27	Passed
26	Passed
25	Failed

Selected Cycles:
31

☑ Short Format
☐ Long Format
☐ Parametric Format
☐ Cycle Graph
☐ One Sec File

Figure 68. Network Transfer Screen.

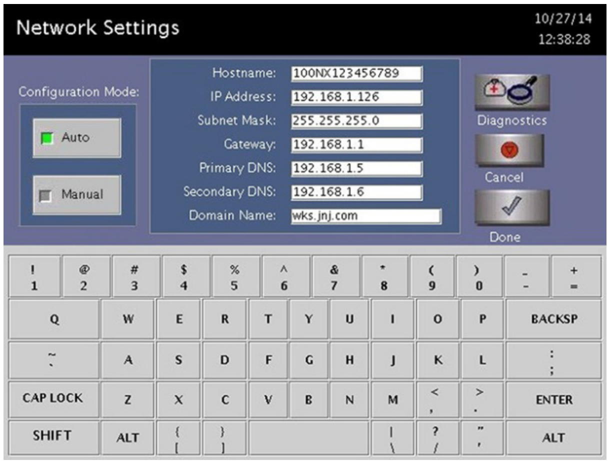
5. Select the cycle(s) from the list of Cycles Available.
6. Select desired PDF printout format **(**Short, Long, Medium, Alarm Limit) and/or One Sec File (.CSV) to transfer.
7. Touch **Transfer**. The files should begin transferring to the computer server. “Transfer in Progress” message is displayed.
8. On the computer server, the files will begin appearing in the shared folder. If no files appear in the shared folder on the computer server, see “Troubleshooting Utilities”.

Section 4.

Troubleshooting Utilities

If the cycle files are not appearing on the computer server or if the number of cycle files pending transfer from the System Ready screen is 10 or more cycles, contact your IT department to perform the following:

1. Check that the Ethernet cable is connected to the sterilizer and to the active data port on the wall.
2. Check and verify that the computer server is up and connected to the network.
3. Check that the settings for the computer server have not changed.
4. Verify the network settings of screens 1 and 2 (see Figures 62 and 63) on the sterilizer match the computer server settings.
5. Navigate to the System Ready screen.
6. Touch **Additional Utilities** on the System Ready screen.
7. Login with a Supervisor Level account.
8. Touch **Network**.



Network Settings

10/27/14
12:38:28

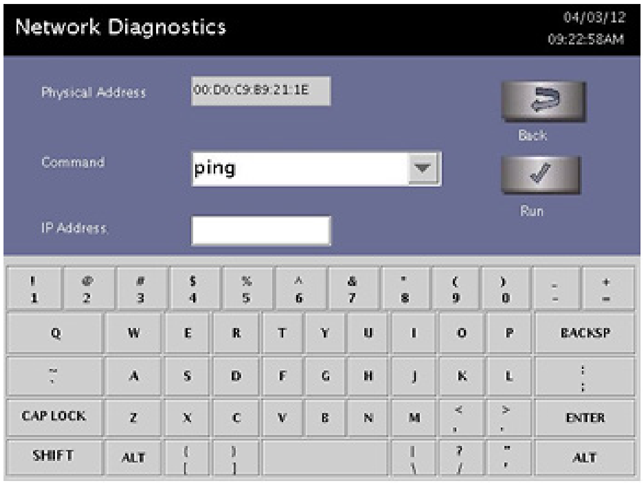
Configuration Mode:
● Auto
○ Manual

Hostname: 100NX123456789
IP Address: 192.168.1.126
Subnet Mask: 255.255.255.0
Gateway: 192.168.1.1
Primary DNS: 192.168.1.5
Secondary DNS: 192.168.1.6
Domain Name: wks.jnj.com

Diagnostics
Cancel
Done
! 1 @ 2 # 3 $ 4 % 5 ^ 6 & 7 * 8 (9) 0 _ - + =
Q W E R T Y U I O P BACKSP
~ ` A S D F G H J K L : ;
CAP LOCK Z X C V B N M < , > . ENTER
SHIFT ALT { [}] | \ ? / " ' ALT

Figure 69. Network Settings 1. The data shown in this screen's field is for context.

9. Touch **Diagnostics**.



Network Diagnostics
04/03/12
09:22:58AM

Physical Address: 00:D0:C9:89:21:1E
Command: ping
IP Address:

Back
Run
! 1 @ 2 # 3 $ 4 % 5 ^ 6 & 7 * 8 (9) 0 _ - + =
Q W E R T Y U I O P BACKSP
~ ` A S D F G H J K L : ;
CAP LOCK Z X C V B N M < , > .
SHIFT ALT { [}] | \ ? / " '
ENTER
ALT

Figure 70. Network Diagnostics Screen. The data shown in this screen's field is for context.

The Command pull down menu has the following utilities

- ping - to test the reachability of a computer server.
- ipconfig - displays all current TCP/IP network configuration values.
- ipconfig /renew - renews as adapters, and displays all current TCP/IP network configuration values.
- netstat - displays network connections (both incoming and outgoing), routing tables, and a number of network interface statistics.
- tracert - displaying the route (path) and measuring transit delays of packets across an Internet Protocol (IP) network.
- nslookup - for querying the DNS to obtain domain name or IP address mapping or for any other specific DNS record.

10. Select a command from the menu and enter in the IP Address/URL.
11. Touch **Run**.
12. Once the network connection has been confirmed, test the network connectivity with a manual cycle transfer. See "Manual Network File Transfer".

Section 5.

Network Message Table

If this message appears…	Do this…
Another Device On The Network Has The Same IP Address. Contact Hospital IT For Assistance.	• Contact hospital IT for assistance. • Confirm that no other device on the network has the same IP address. • Change the IP address.
Cannot Connect To The Remote PC/Server. Confirm That The Network Cable Is Plugged In. Contact Hospital IT For Assistance.	• Contact the hospital IT for assistance. • Check that the network cable is plugged in to the sterilizer and to the active data port on the wall. • Check that the network settings on the sterilizer are correct. • Check that the computer server information is correct and has not been changed.
Cannot Locate DHCP Server. Contact Hospital IT For Assistance.	• Contact hospital IT for assistance. • Check that the DHCP server is operational.
Enter A Valid Hostname (alphanumeric and "_"). Hostname Must Be Unique. Contact Hospital IT For Assistance.	• Contact hospital IT for assistance. • Confirm that the Hostname is the default STERRAD® 100NX® Hostname or uses alphanumeric characters and "_".
Error In File Generation	• The sterilizer is unable to create files for the selected cycle. Select a different cycle number to transfer.
Error In File Transfer	• Contact the hospital IT for assistance. • Check that the computer server information is correct and has not been changed.
Error In Network File Transfer. The Oldest Cycle Record Will Be Deleted.	• Contact the hospital IT for assistance. • Check that the computer server information is correct and has not been changed.

If this message appears…	Do this…
Feature Is Not Available Or Network Is Not Configured Properly. Please Call ASP Representative For More Information	• Confirm network settings are configured. • Contact ASP Representative for more information.
Feature is Not Available. Please Call ASP Representative For More Information	• Contact ASP Representative for more information.
Network Cable Is Disconnected. Confirm That The Network Cable Is Plugged In. Contact Hospital IT For Assistance.	• Check that the network cable is plugged in to the sterilizer and to the active data port on the wall. • Run Ping in Diagnostics to verify connectivity.
Please Enter A Valid DNS IP Address. The Format Is Four Numbers Between 0 And 255 Separated By Periods. Contact Hospital IT For Assistance.	• Contact the hospital IT for assistance. • Verify the values entered.
Please Enter A Valid domain name. Contact Hospital IT For Assistance.	• Contact the hospital IT for assistance. • Verify the values entered do not exceed 30 characters.
Please Enter A Valid Gateway Address. The Format Is Four Numbers Between 0 And 255 Separated By Periods. Contact Hospital IT For Assistance.	• Contact the hospital IT for assistance. • Verify the values entered.
Please Enter A Valid IP Address. The Format Is Four Numbers Between 0 And 255 Separated By Periods. Contact Hospital IT For Assistance.	• Contact the hospital IT for assistance. • Verify the values entered.
Please Enter A Valid Subnet Mask. The Format Is Four Numbers Between 0 And 255 Separated By Periods. Contact Hospital IT For Assistance.	• Contact the hospital IT for assistance. • Verify the values entered.
Unable To Establish Connection	• Contact the hospital IT for assistance. • Check that the network cable is plugged in to the sterilizer and to the active port on the wall. • Check that the network settings on the sterilizer are correct. • Check that the computer server information is correct and has not been changed.

If this message appears…	Do this…
Unable To Establish Connection. Confirm Entered Settings Are Correct. Contact Hospital IT For Assistance.	• Contact the hospital IT for assistance. • Check that the network settings on the sterilizer are correct. • Check that the computer server information is correct and has not been changed. • Ensure service account name and password have not changed.

Section 6.

Testing the Network Connection

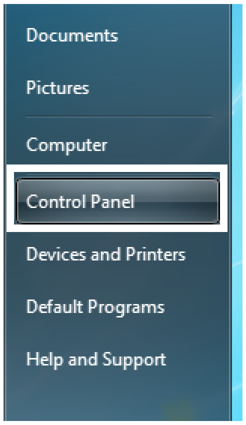
To ensure that the STERRAD® 100NX® can send data to the network, a "ping" test can be performed. A network crossover cable is required for this test.

The steps below are using Windows® 7, operating system. If you are using a different version of Windows, your screens may look different.

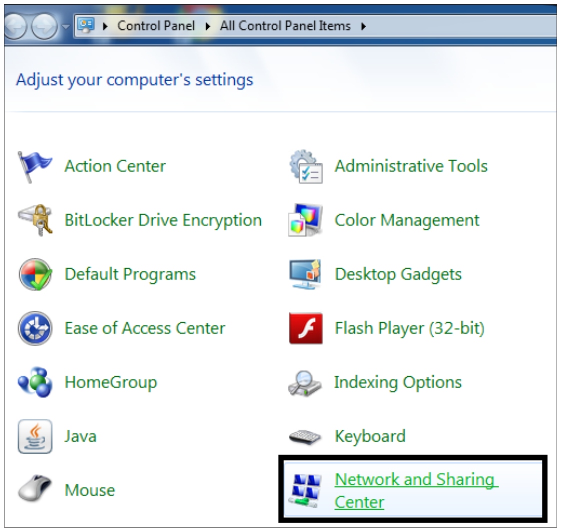
A. Preparing the Remote Host Computer for the Ping Test

Before the test is run a Local Area Network (LAN) connection must be created.

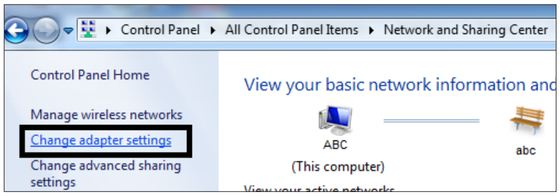
1. Connect the crossover cable to the remote host computer and to the STERRAD® 100NX® sterilizer.
2. Press the (start icon) on the Windows® 7 taskbar and select **Control Panel**.


Documents
Pictures
Computer
Control Panel
Devices and Printers
Default Programs
Help and Support

3. Select **Network and Sharing Center**.


Control Panel ▸ All Control Panel Items ▸
Adjust your computer's settings
Action Center
Administrative Tools
BitLocker Drive Encryption
Color Management
Default Programs
Desktop Gadgets
Ease of Access Center
Flash Player (32-bit)
HomeGroup
Indexing Options
Java
Keyboard
Mouse
Network and Sharing Center

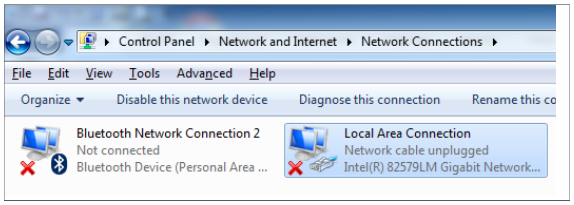
4. Select **Change Adapter Settings**.


Control Panel ▸ All Control Panel Items ▸ Network and Sharing Center
Control Panel Home
Manage wireless networks
Change adapter settings
Change advanced sharing settings
View your basic network information and
ABC
(This computer)
abc

5.

   a. Select **Local Area Connection**.

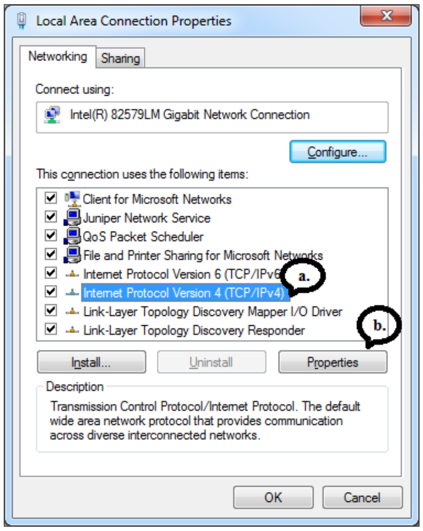
   b. Press **Properties** (not shown).


Control Panel ▸ Network and Internet ▸ Network Connections ▸
File Edit View Tools Advanced Help
Organize ▾
Disable this network device
Diagnose this connection
Rename this co
Bluetooth Network Connection 2
Not connected
Bluetooth Device (Personal Area ...
Local Area Connection
Network cable unplugged
Intel(R) 82579LM Gigabit Network...

6.

   a. Select **Internet Protocol Version 4 (TCP/IPv4)**.

   b. Press **Properties**.


Local Area Connection Properties
Networking
Sharing
Configure...
Install...
Uninstall
Properties
OK
Cancel
a.
b.

Connect using:

Intel(R) 82579LM Gigabit Network Connection

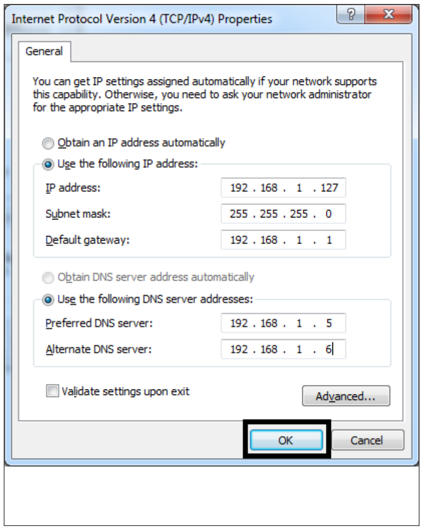
This connection uses the following items:

- ☑ Client for Microsoft Networks
- ☑ Juniper Network Service
- ☑ QoS Packet Scheduler
- ☑ File and Printer Sharing for Microsoft Networks
- ☑ Internet Protocol Version 6 (TCP/IPv6)
- ☑ Internet Protocol Version 4 (TCP/IPv4)
- ☑ Link-Layer Topology Discovery Mapper I/O Driver
- ☑ Link-Layer Topology Discovery Responder

Description

Transmission Control Protocol/Internet Protocol. The default wide area network protocol that provides communication across diverse interconnected networks.

7. Select **Use the following IP address**: and then enter the following sample network number information.
   IP Address (**192.168.1.127**),
   Subnet Mask (**255.255.255.0**),
   Default gateway (**192.168.1.1**),
   Preferred DNS server (**192.168.1.5**),
   Alternate DNS server (**192.168.1.6**).
   Press **OK**.


Internet Protocol Version 4 (TCP/IPv4) Properties
General
Advanced...
OK
Cancel

You can get IP settings assigned automatically if your network supports this capability. Otherwise, you need to ask your network administrator for the appropriate IP settings.

○ Obtain an IP address automatically
● Use the following IP address:
IP address: 192 . 168 . 1 . 127
Subnet mask: 255 . 255 . 255 . 0
Default gateway: 192 . 168 . 1 . 1

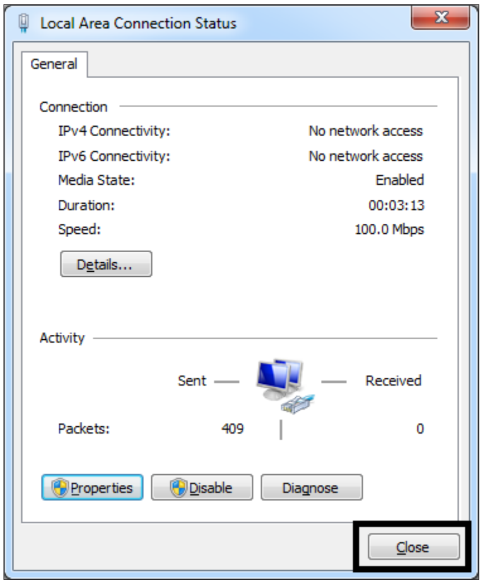
○ Obtain DNS server address automatically
● Use the following DNS server addresses:
Preferred DNS server: 192 . 168 . 1 . 5
Alternate DNS server: 192 . 168 . 1 . 6

☐ Validate settings upon exit

8.

a. Press **Close** on the “Local Area Connection Status”.

b. Press **Close** on the next screen.



Local Area Connection Status

Connection

IPv4 Connectivity: No network access

IPv6 Connectivity: No network access

Media State: Enabled

Duration: 00:03:13

Speed: 100.0 Mbps

Activity

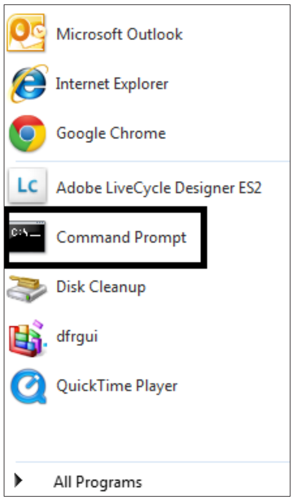
Packets: Sent 409 Received 0

General
Details...
Sent
Received
Properties
Disable
Diagnose
Close

9.

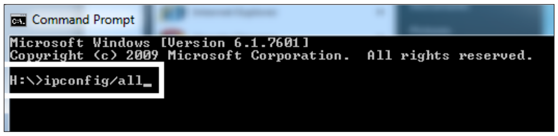
a. You can verify that the LAN information is correct.

From the taskbar, click on the (start icon).
Select **Command Prompt** from the list of programs.



Microsoft Outlook
Internet Explorer
Google Chrome
Adobe LiveCycle Designer ES2
Command Prompt
Disk Cleanup
dfrgui
QuickTime Player
All Programs

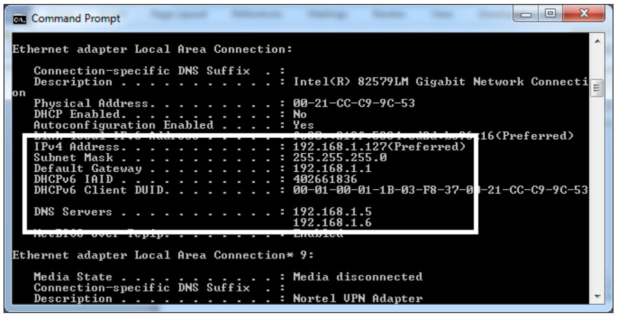
b. As shown in the example, enter **ipconfig/all** after “(Drive letter):\>”. Press **Enter** on the computer’s keyboard.



Command Prompt

```
Microsoft Windows [Version 6.1.7601]
Copyright (c) 2009 Microsoft Corporation.  All rights reserved.

H:\>ipconfig/all_
```

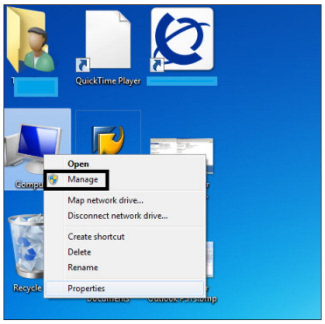
c. This screen will display. If the LAN was set up correctly, the network information you entered in step 7 will be on the screen. The ping test can be run from the sterilizer.


Command Prompt

```
Ethernet adapter Local Area Connection:

   Connection-specific DNS Suffix  . :
   Description . . . . . . . . . . . : Intel(R) 82579LM Gigabit Network Connecti
on
   Physical Address. . . . . . . . . : 00-21-CC-C9-9C-53
   DHCP Enabled. . . . . . . . . . . : No
   Autoconfiguration Enabled . . . . : Yes
   Link-local IPv6 Address . . . . . : [illegible]16(Preferred)
   IPv4 Address. . . . . . . . . . . : 192.168.1.127(Preferred)
   Subnet Mask . . . . . . . . . . . : 255.255.255.0
   Default Gateway . . . . . . . . . : 192.168.1.1
   DHCPv6 IAID . . . . . . . . . . . : 402661836
   DHCPv6 Client DUID. . . . . . . . : 00-01-00-01-1B-03-F8-37-0[illegible]-21-CC-C9-9C-53

   DNS Servers . . . . . . . . . . . : 192.168.1.5
                                       192.168.1.6
   NetBIOS over Tcpip. . . . . . . . : Enabled

Ethernet adapter Local Area Connection* 9:

   Media State . . . . . . . . . . . : Media disconnected
   Connection-specific DNS Suffix  . :
   Description . . . . . . . . . . . : Nortel VPN Adapter
```

B. Temporarily Turning Off the Windows Security Feature on the Remote Host Computer

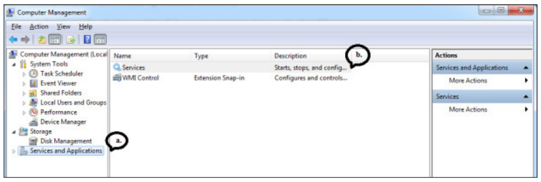
1. From the desktop, right click on the **Computer** icon and select **Manage**.


QuickTime Player
Open
Manage
Map network drive...
Disconnect network drive...
Create shortcut
Delete
Rename
Properties
Recycle

2.

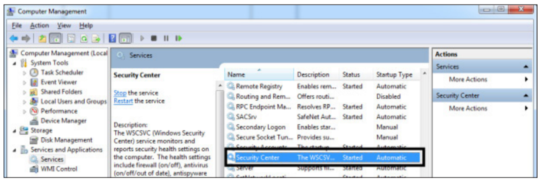
a. Select **Services and Applications** from the options on the left side of the screen.

b. Double-click on **Services**.


Computer Management
File Action View Help
Computer Management (Local
System Tools
Task Scheduler
Event Viewer
Shared Folders
Local Users and Groups
Performance
Device Manager
Storage
Disk Management
Services and Applications
a.
b.
Actions
Services and Applications
More Actions
Services
More Actions

Name	Type	Description
Services		Starts, stops, and config...
WMI Control	Extension Snap-in	Configures and controls...

3. Double click on **Security Center**.


Computer Management
File Action View Help
Computer Management (Local
System Tools
Task Scheduler
Event Viewer
Shared Folders
Local Users and Groups
Performance
Device Manager
Storage
Disk Management
Services and Applications
Services
WMI Control
Services
Security Center
Stop the service
Restart the service
Actions
Services
More Actions
Security Center
More Actions

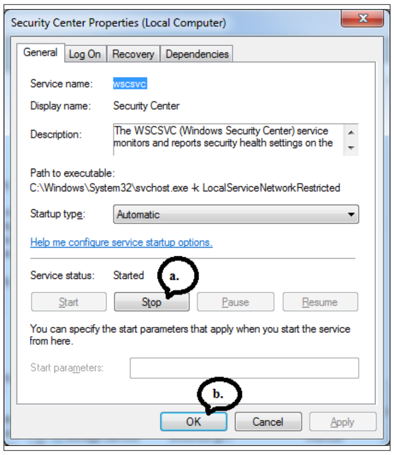
Description:
The WSCSVC (Windows Security Center) service monitors and reports security health settings on the computer. The health settings include firewall (on/off), antivirus (on/off/out of date), antispyware

Name	Description	Status	Startup Type
Remote Registry	Enables rem...	Started	Automatic
Routing and Rem...	Offers routi...		Disabled
RPC Endpoint Ma...	Resolves RP...	Started	Automatic
SACSrv	SafeNet Aut...	Started	Automatic
Secondary Logon	Enables star...		Manual
Secure Socket Tun...	Provides su...		Manual
Security Accounts...	The startup...	Started	Automatic
Security Center	The WSCSV...	Started	Automatic
Server	Supports fil...	Started	Automatic

4.

a. Press **Stop** in the Service status field.

b. Press **OK** to close the screen.


Security Center Properties (Local Computer)
General
Log On
Recovery
Dependencies
Help me configure service startup options.
a.
Start
Stop
Pause
Resume
Start parameters:
b.
OK
Cancel
Apply

Service name: wscsvc

Display name: Security Center

Description: The WSCSVC (Windows Security Center) service monitors and reports security health settings on the

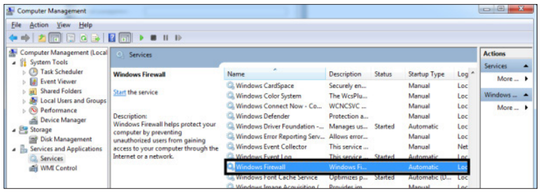
Path to executable:
C:\Windows\System32\svchost.exe -k LocalServiceNetworkRestricted

Startup type: Automatic

Service status: Started

You can specify the start parameters that apply when you start the service from here.

5. Scroll down the menu options and double click on **Windows Firewall**.


Computer Management
File
Action
View
Help
Computer Management (Local
System Tools
Task Scheduler
Event Viewer
Shared Folders
Local Users and Groups
Performance
Device Manager
Storage
Disk Management
Services and Applications
Services
WMI Control
Services
Windows Firewall
Start the service
Actions
Services
More ...
Windows ...
More ...

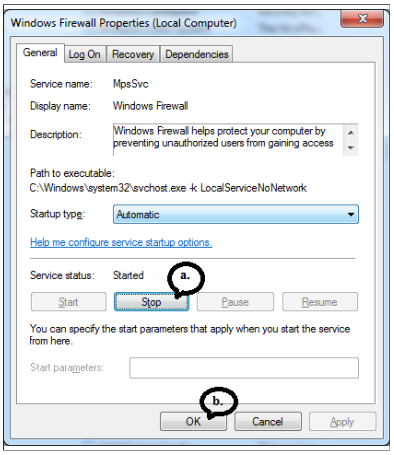
Description:
Windows Firewall helps protect your computer by preventing unauthorized users from gaining access to your computer through the Internet or a network.

Name	Description	Status	Startup Type	Log
Windows CardSpace	Securely en...		Manual	Loc
Windows Color System	The WcsPlu...		Manual	Loc
Windows Connect Now - Co...	WCNCSVC ...		Manual	Loc
Windows Defender	Protection a...		Manual	Loc
Windows Driver Foundation -...	Manages us...	Started	Automatic	Loc
Windows Error Reporting Serv...	Allows error...		Manual	Loc
Windows Event Collector	This service ...		Manual	Net
Windows Event Log	This service ...	Started	Automatic	Loc
Windows Firewall	Windows Fi...		Automatic	Loc
Windows Font Cache Service	Optimizes p...	Started	Automatic (D...	Loc

6.

a. Press **Stop** in the Service status field

b. Click **OK** to close the screen.


Windows Firewall Properties (Local Computer)
General
Log On
Recovery
Dependencies
Help me configure service startup options.
a.
Start
Stop
Pause
Resume
Start parameters:
b.
OK
Cancel
Apply

Service name: MpsSvc

Display name: Windows Firewall

Description: Windows Firewall helps protect your computer by preventing unauthorized users from gaining access

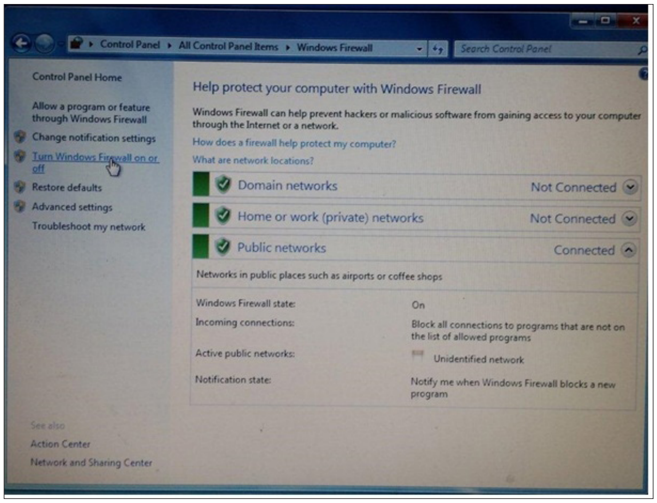
Path to executable:
C:\Windows\system32\svchost.exe -k LocalServiceNoNetwork

Startup type: Automatic

Service status: Started

You can specify the start parameters that apply when you start the service from here.

7. Turn off Windows Firewall.
    a. Click **Windows START**, **Control Panel**, **Windows Firewall**.
    b. Click Turn **Windows Firewall On or Off** on the side panel of the Windows screen.


Control Panel ▸ All Control Panel Items ▸ Windows Firewall
Search Control Panel
Control Panel Home
Allow a program or feature through Windows Firewall
Change notification settings
Turn Windows Firewall on or off
Restore defaults
Advanced settings
Troubleshoot my network
See also
Action Center
Network and Sharing Center

Help protect your computer with Windows Firewall

Windows Firewall can help prevent hackers or malicious software from gaining access to your computer through the Internet or a network.

How does a firewall help protect my computer?

What are network locations?

Domain networks Not Connected

Home or work (private) networks Not Connected

Public networks Connected

Networks in public places such as airports or coffee shops

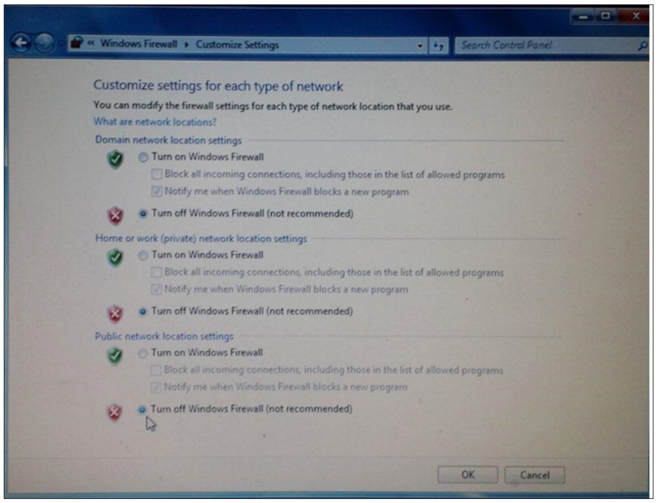
Windows Firewall state: On

Incoming connections: Block all connections to programs that are not on the list of allowed programs

Active public networks: Unidentified network

Notification state: Notify me when Windows Firewall blocks a new program

8. Click on **User Recommended Settings**, select the radio button **Turn off Windows Firewall** from each of the following section:
    a. Domain network location settings
    b. Home or work (private) network location settings
    c. Public network location settings
    d. Press OK.


Windows Firewall ▸ Customize Settings
Search Control Panel
OK
Cancel

Customize settings for each type of network

You can modify the firewall settings for each type of network location that you use.

What are network locations?

Domain network location settings
○ Turn on Windows Firewall
☐ Block all incoming connections, including those in the list of allowed programs
☑ Notify me when Windows Firewall blocks a new program
● Turn off Windows Firewall (not recommended)

Home or work (private) network location settings
○ Turn on Windows Firewall
☐ Block all incoming connections, including those in the list of allowed programs
☑ Notify me when Windows Firewall blocks a new program
● Turn off Windows Firewall (not recommended)

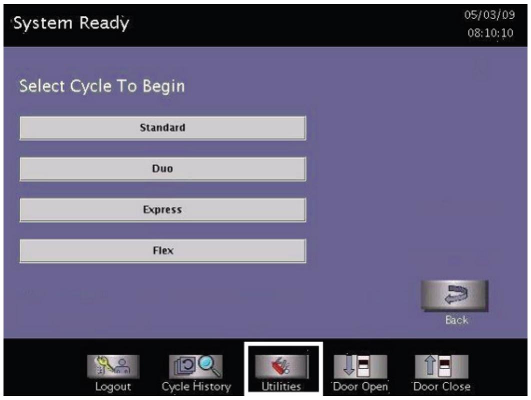
Public network location settings
○ Turn on Windows Firewall
☐ Block all incoming connections, including those in the list of allowed programs
☑ Notify me when Windows Firewall blocks a new program
● Turn off Windows Firewall (not recommended)

C. Running the Ping Test from the Sterilizer

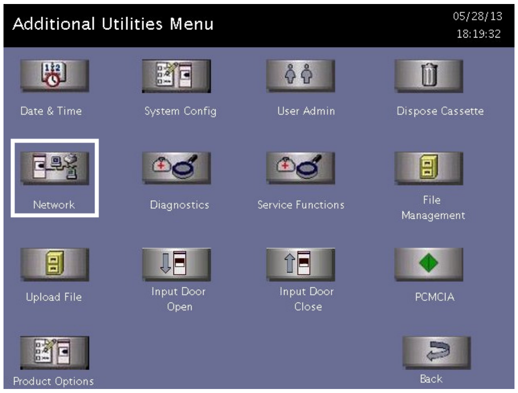
✓ ***Note:*** *Supervisor Level Access is required for this procedure.*

These steps are performed to show that the sterilizer can send data packets to the network.

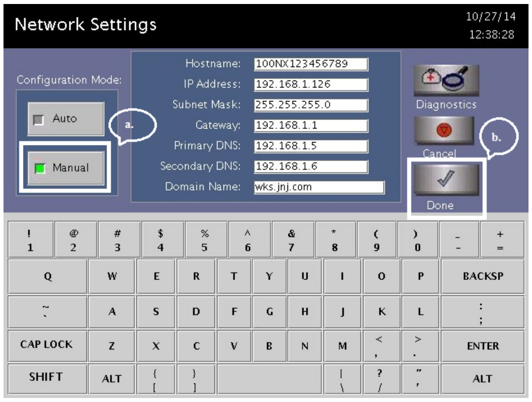
1. Navigate to the System Ready Screen and press Additional **Utilities**.


System Ready
05/03/09
08:10:10
Select Cycle To Begin
Standard
Duo
Express
Flex
Back
Logout
Cycle History
Utilities
Door Open
Door Close

2. Press **Network** on the “Additional Utilities Menu”.


Additional Utilities Menu
05/28/13
18:19:32
Date & Time
System Config
User Admin
Dispose Cassette
Network
Diagnostics
Service Functions
File Management
Upload File
Input Door Open
Input Door Close
PCMCIA
Product Options
Back

3.

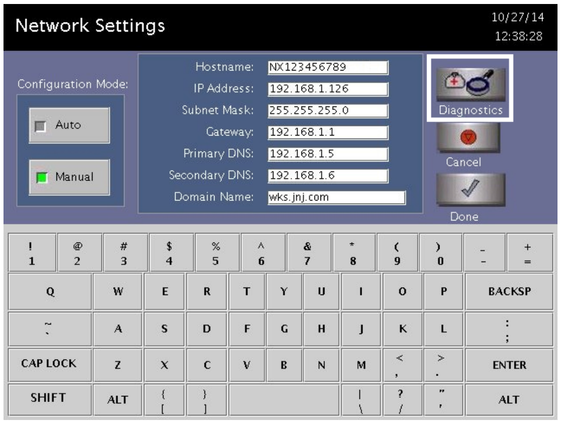

Network Settings
10/27/14
12:38:28
Configuration Mode:
Auto
Manual
a.
Diagnostics
Cancel
b.
Done
CAP LOCK
SHIFT
ALT
BACKSP
ENTER

Hostname: 100NX123456789
IP Address: 192.168.1.126
Subnet Mask: 255.255.255.0
Gateway: 192.168.1.1
Primary DNS: 192.168.1.5
Secondary DNS: 192.168.1.6
Domain Name: wks.jnj.com

   a. Press **Manual** in the Configuration Mode of the Network Settings screen.
   Enter the following information for the fields in the screen.
   For the Hostname you can use the information from F-107773 (Digital Transfer Interface Network Connection Information form).
   IP Address (**192.168.1.126**),
   Subnet Mask (**255.255.255.0**),
   Gateway (**192.168.1.1**),
   Primary DNS (**192.168.1.5**),
   Secondary DNS (**192.168.1.6**).
   For the Domain Name you can use the information from F-107773 (Digital Transfer Interface network Connection Information form) or leave as blank.

   b. Press **Done** to save the network data.

4. Press **Diagnostics** on the Network Settings Screen.



Network Settings

10/27/14
12:38:28

Configuration Mode:

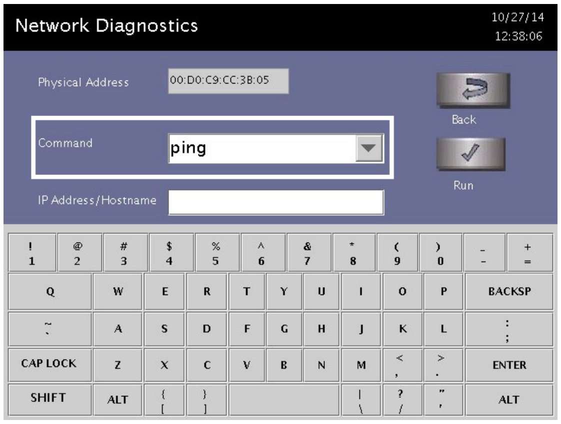
☐ Auto

☑ Manual

Hostname: NX123456789
IP Address: 192.168.1.126
Subnet Mask: 255.255.255.0
Gateway: 192.168.1.1
Primary DNS: 192.168.1.5
Secondary DNS: 192.168.1.6
Domain Name: wks.jnj.com

Diagnostics
Cancel
Done
! 1 @ 2 # 3 $ 4 % 5 ^ 6 & 7 * 8 (9) 0 _ - + =
Q W E R T Y U I O P BACKSP
~ ` A S D F G H J K L : ;
CAP LOCK Z X C V B N M < , > . ENTER
SHIFT ALT { [}] | \ ? / " ' ALT

5. Select **ping** from the pull down “Command” options choices.



Network Diagnostics

10/27/14
12:38:06

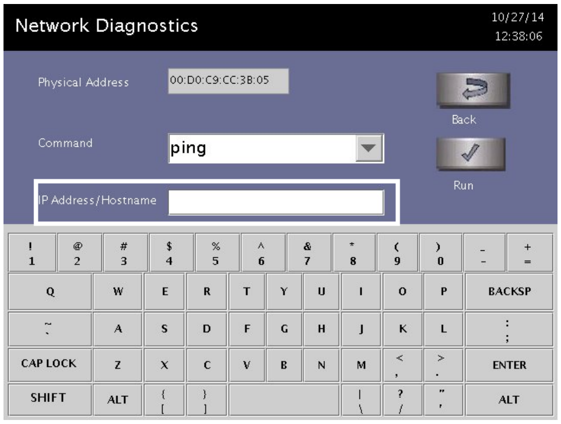
Physical Address: 00:D0:C9:CC:3B:05

Command: ping

IP Address/Hostname:

Back
Run
! 1 @ 2 # 3 $ 4 % 5 ^ 6 & 7 * 8 (9) 0 _ - + =
Q W E R T Y U I O P BACKSP
~ ` A S D F G H J K L : ;
CAP LOCK Z X C V B N M < , > . ENTER
SHIFT ALT { [}] | \ ? / " ' ALT

6. Enter the remote host computer’s IP address as **192.168.1.127** in the “IP Address /Hostname” field.



Network Diagnostics

10/27/14
12:38:06

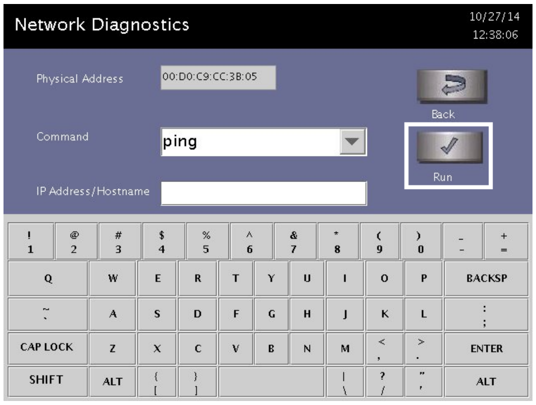
Physical Address: 00:D0:C9:CC:3B:05

Command: ping

IP Address/Hostname:

Back
Run
! 1 @ 2 # 3 $ 4 % 5 ^ 6 & 7 * 8 (9) 0 _ - + =
Q W E R T Y U I O P BACKSP
~ ` A S D F G H J K L : ;
CAP LOCK Z X C V B N M < , > . ENTER
SHIFT ALT { [}] | \ ? / " ' ALT

7. Press **Run**. The sterilizer performs a network ping test by sending 10 data packets to the remote host computer.



Network Diagnostics
10/27/14
12:38:06
Back
Run
! 1 @ 2 # 3 $ 4 % 5 ^ 6 & 7 * 8 (9) 0 _ - + =
Q W E R T Y U I O P BACKSP
~ ` A S D F G H J K L : ;
CAP LOCK Z X C V B N M < , > . ENTER
SHIFT ALT { [}] | \ ? / " ' ALT

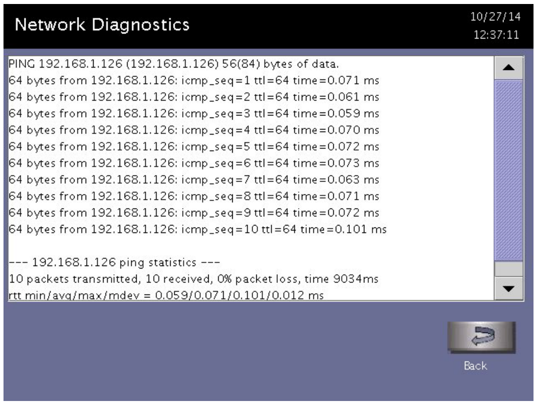
Physical Address 00:D0:C9:CC:3B:05

Command ping

IP Address/Hostname

8. If the sterilizer's ping test is successful from the sterilizer, then the messages from the 10 packets will display.

   If it isn't successful, verify that all the information was entered correctly and re-run the test.



Network Diagnostics
10/27/14
12:37:11
Back

```
PING 192.168.1.126 (192.168.1.126) 56(84) bytes of data.
64 bytes from 192.168.1.126: icmp_seq=1 ttl=64 time=0.071 ms
64 bytes from 192.168.1.126: icmp_seq=2 ttl=64 time=0.061 ms
64 bytes from 192.168.1.126: icmp_seq=3 ttl=64 time=0.059 ms
64 bytes from 192.168.1.126: icmp_seq=4 ttl=64 time=0.070 ms
64 bytes from 192.168.1.126: icmp_seq=5 ttl=64 time=0.072 ms
64 bytes from 192.168.1.126: icmp_seq=6 ttl=64 time=0.073 ms
64 bytes from 192.168.1.126: icmp_seq=7 ttl=64 time=0.063 ms
64 bytes from 192.168.1.126: icmp_seq=8 ttl=64 time=0.071 ms
64 bytes from 192.168.1.126: icmp_seq=9 ttl=64 time=0.072 ms
64 bytes from 192.168.1.126: icmp_seq=10 ttl=64 time=0.101 ms

--- 192.168.1.126 ping statistics ---
10 packets transmitted, 10 received, 0% packet loss, time 9034ms
rtt min/avg/max/mdev = 0.059/0.071/0.101/0.012 ms
```

The ping test is complete.

D. Reset the LAN Settings on your Laptop

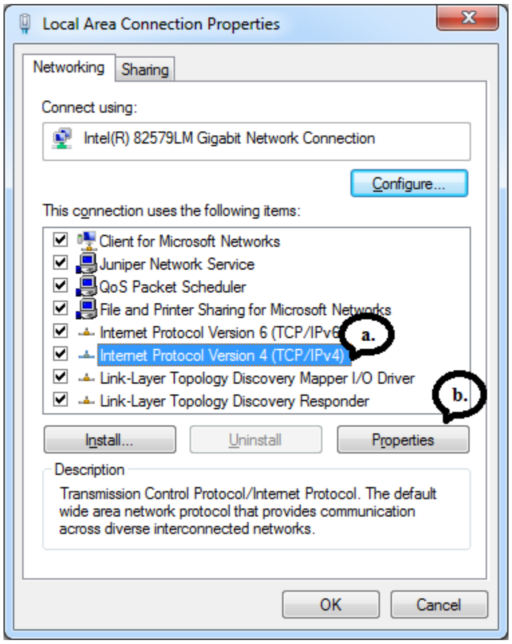
After the ping test is complete, you will need to reset the LAN network properties on your laptop.

1\.

   a. Go to the Local Area Connection Properties screen. Select **Internet Protocol Version 4 (TCP/ IPv4)**.

   b. Press **Properties**.

   c. Press **OK**.


Local Area Connection Properties
Networking
Sharing
Configure...
Install...
Uninstall
Properties
OK
Cancel
a.
b.

Connect using:

Intel(R) 82579LM Gigabit Network Connection

This connection uses the following items:

- ☑ Client for Microsoft Networks
- ☑ Juniper Network Service
- ☑ QoS Packet Scheduler
- ☑ File and Printer Sharing for Microsoft Networks
- ☑ Internet Protocol Version 6 (TCP/IPv6)
- ☑ Internet Protocol Version 4 (TCP/IPv4)
- ☑ Link-Layer Topology Discovery Mapper I/O Driver
- ☑ Link-Layer Topology Discovery Responder

Description

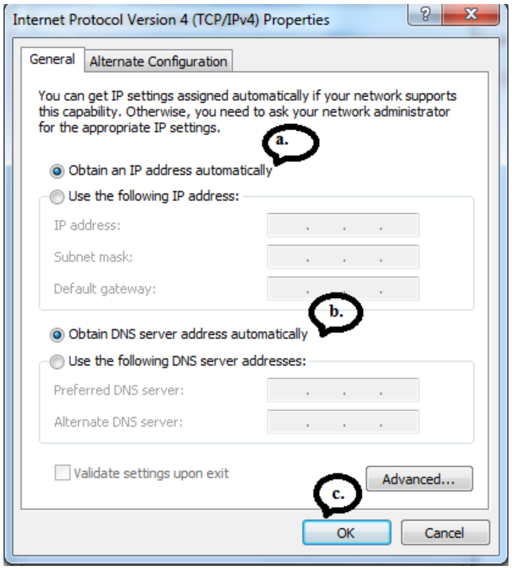
Transmission Control Protocol/Internet Protocol. The default wide area network protocol that provides communication across diverse interconnected networks.

2\.

   a. Select **Obtain an IP address automatically**.

   b. Select **Obtain DNS server addresses automatically**.

   c. Press **OK**.

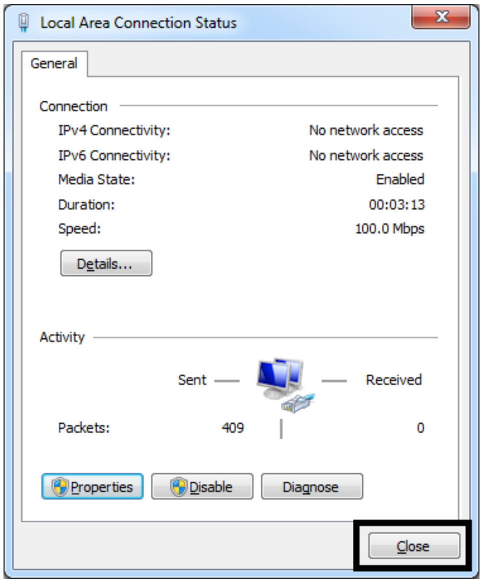

Internet Protocol Version 4 (TCP/IPv4) Properties
General
Alternate Configuration
Advanced...
OK
Cancel
a.
b.
c.

You can get IP settings assigned automatically if your network supports this capability. Otherwise, you need to ask your network administrator for the appropriate IP settings.

- ● Obtain an IP address automatically
- ○ Use the following IP address:
  - IP address: . . .
  - Subnet mask: . . .
  - Default gateway: . . .
- ● Obtain DNS server address automatically
- ○ Use the following DNS server addresses:
  - Preferred DNS server: . . .
  - Alternate DNS server: . . .

☐ Validate settings upon exit

3. Press **Close** on the "Local Area Connection Status".



Local Area Connection Status

General

Connection

IPv4 Connectivity: No network access
IPv6 Connectivity: No network access
Media State: Enabled
Duration: 00:03:13
Speed: 100.0 Mbps

Activity

Sent — — Received

Packets: 409 | 0

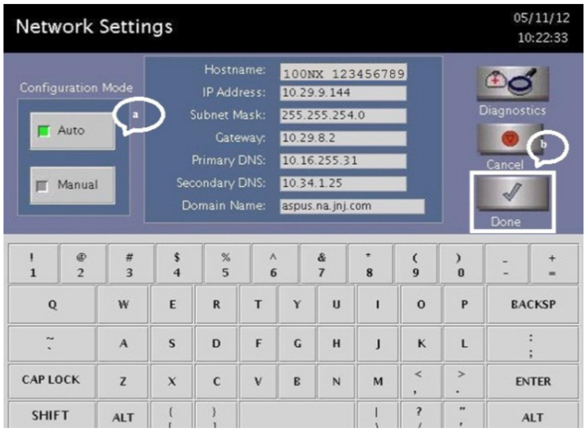
X
Details...
Properties
Disable
Diagnose
Close

Reboot the computer to complete the reset of the LAN.

E. Reset the Network Settings of the Sterilizer

These steps are performed to reset the network settings of the sterilizer. Disconnect the cross-over network cable from the network port of the sterilizer and connect the customer's LAN straight network cable.

1. Navigate back to the Network Settings screen.
    a. Press **Auto** in the Configuration Mode of the Network Settings screen.
    b. Press **Done**. (If you use "Manual" configuration you must restore the settings manually.)
2. Reboot the sterilizer.



Network Settings

05/11/12
10:22:33

Hostname: 100NX 123456789
IP Address: 10.29.9.144
Subnet Mask: 255.255.254.0
Gateway: 10.29.8.2
Primary DNS: 10.16.255.31
Secondary DNS: 10.34.1.25
Domain Name: aspus.na.jnj.com

Configuration Mode
Auto
Manual
a
Diagnostics
Cancel
b
Done
BACKSP
CAP LOCK
ENTER
SHIFT
ALT
ALT